

Management Discussion & Analysis for the Fourth Quarter of FY 2019-20

Revenue Figures for the Consolidated Glenmark Pharmaceuticals Ltd.

(Rs. In Millions)

	Fourth Quarter ended March 31			For the Year ended March 31		
	FY 2019-20	FY 2018-19	Growth (%)	FY 2019-20	FY 2018-19	Growth (%)
India	7,647.53	6,677.94	14.52%	32,021.67	27,769.71	15.31%
North America	7,619.02	7,696.00	-1.00%	31,404.49	31,392.70	0.04%
Rest of the World (ROW)	3,365.47	3,852.85	-12.65%	12,854.45	12,759.35	0.75%
Europe	4,115.68	3,184.07	29.26%	12,484.48	11,207.09	11.40%
Latin America	1,768.73	1,204.07	46.90%	5,355.57	4,179.53	28.14%
API	2,613.79	2,487.77	5.07%	10,239.17	9,493.11	7.86%
Total	27,130.22	25,102.70	8.08%	104,359.83	96,801.49	7.81%
Other Revenue	544.67	532.04	2.37%	2,049.86	1,853.20	10.61%
Consolidated Revenue	27,674.89	25,634.74	7.96%	106,409.69	98,654.69	7.86%

Average conversion rate in 12M FY 2019-20 considered as INR 70.78 /USD 1.00

Average conversion rate in 12M FY 2018-19 considered as INR 69.76/USD 1.00

USD figures are only indicative

Review of Operations for the quarter ended March 31, 2020

For the Fourth Quarter of FY 2019-20, Glenmark's consolidated revenue was at Rs. **27,674.89** Mn (USD 382.61 Mn) as against Rs. **25,634.74** Mn (USD 364.61 Mn) recording an increase of 7.96%.

For the year ended Mar 31, 2020, Glenmark's consolidated revenue was at Rs. **106,409.69** Mn (USD 1503.39 Mn) as against Rs. **98,654.69** Mn (USD 1414.20 Mn) recording an increase of 7.86%.

Business update on account of the COVID situation

The COVID-19 pandemic and the subsequent lockdown across India affected Glenmark production facilities in the months of March and April. However, by the end of April Glenmark's manufacturing units managed to stabilise production and logistics were also in place in order to ensure uninterrupted supplies to all our markets. As of now, all of Glenmark's manufacturing facilities are operational and the supply of raw materials has also improved significantly. Further, internal logistics within India were stabilised by end April and exports to all markets resumed to a significant extent by first week of May. Since the start of the outbreak, Glenmark employees across operations around the world have worked round-the-clock to formulate and adopt best practices that adhere to the highest standards of safety. Glenmark employees have also facilitated the uninterrupted supply of medicines to every market it services. The Company has made significant efforts to reduce the burden on the community on account of COVID-19 across its operational countries and manufacturing locations. The details are available on the company's website.

In a landmark development for COVID-19 patients in India, Glenmark announced the launch of an antiviral drug Favipiravir (brand name FabiFlu®) for the treatment of mild to moderate COVID-19 patients. Glenmark received manufacturing and marketing approval from India's drug regulator as part of accelerated approval process, considering the emergency situation of the COVID-19 outbreak in India. The approval's restricted use entails responsible medication use where every patient must have signed informed consent before treatment initiation. Glenmark's approval from India's drug regulator, makes FabiFlu® the first oral Favipiravir-approved medication in India for the treatment of COVID-19. Favipiravir is backed by clinical evidence showing encouraging results in patients with mild to moderate COVID-19. The antiviral offers broad spectrum RNA virus coverage with clinical improvement noted across age groups 20 to upto 90 years. Favipiravir can be used in COVID-19 patients with co-morbid conditions such as diabetes and heart disease with mild to moderate COVID-19 symptoms. It offers rapid reduction in viral load within 4 days and provides faster symptomatic and radiological improvement. Favipiravir has shown clinical improvement of up to 88% in COVID-19 mild to moderate cases. Glenmark successfully developed the Active Pharmaceutical Ingredient (API) and the formulation for FabiFlu® through its own in-house R&D team. In April 2020, Glenmark filed the product for clinical trial with India's drug regulator DCGI and became the first pharmaceutical company in India to receive approval for conducting Phase 3 clinical trial on mild to moderate COVID-19 patients.

Glenmark would be conducting a post marketing study as recommended by the Indian Drug Regulator on Favipiravir on 1000 patients of mild to moderate COVID-19 for further evaluation of safety and efficacy,

Further, Glenmark also recently announced a new randomized, open-label study to test the combined efficacy of two antiviral drugs Favipiravir and Umifenovir as a potential COVID-19 treatment strategy. The two antiviral drugs have different mechanism of action, and their combination may demonstrate improved treatment efficacy by effectively tackling high viral loads in patients during early stage of disease. Early administration of a combination of antiviral medications acting by different mechanisms is desirable for the treatment of COVID-19, since the viral load of SARS-CoV-2 peaks around the time of symptom onset. Thus combining antiviral drugs could result in greater clinical effectiveness and could also prevent, or delay, the emergence of resistance. Favipiravir is an oral antiviral drug approved in Japan since 2014 for the treatment of novel or re-emerging influenza virus infections. It has a unique mechanism of action by which it inhibits viral replication: it is converted into an active phosphoribosylated form (Favipiravir-RTP) in cells and recognized as a substrate by viral RNA polymerase, thereby inhibiting RNA polymerase activity that is required for viral replication. Umifenovir is another oral antiviral drug licensed for the treatment and prophylaxis of influenza A and B infections in Russia and China. Umifenovir impedes the viral attachment to cells and acts as a viral entry inhibitor. The new combination clinical trial will be called FAITH – (FAVipiravir plus Um I fenovir (efficacy& safety) Trial in Indian Hospital setting). 158 hospitalized patients of moderate COVID-19 infection will be enrolled in the combination study and randomized in two groups: one group receiving Favipiravir and Umifenovir (with standard supportive care); and one group receiving Favipiravir along with standard supportive care.

GLENMARK PHARMACEUTICALS LTD. (GPL)

GPL is primarily focused on building a global Generics, Specialty and OTC business in the therapy areas of Dermatology, Respiratory and Oncology. It also has strong regional/country-specific presence in other therapeutic areas like diabetes, cardiovascular and oral contraceptives.

India

Sales from the formulation business in India for the Fourth Quarter of FY 2019-20 was at Rs. 7,647.53 Mn (USD 105.45 Mn) as against Rs. 6,677.94 Mn (USD 94.9 Mn) in the previous corresponding quarter, recording growth of 14.52%.

The India business continued to outperform the industry growth; as per IQVIA Q4 FY 2019-20, Glenmark's India business recorded growth of 15.90% compared to IPM growth of 9.68%. As per IQVIA MAT March 2020, the India business recorded growth of 14.22% compared to IPM growth of 10.55%. Glenmark's India Formulation business is ranked 14th, with market share of 2.20%. Glenmark has 9 brands among the 'Top 300 Brands in the IPM'.

In terms of market share, Glenmark's India business further strengthened in its core therapy areas such as Cardiac, Diabetes and Respiratory. As per IQVIA MAT March 2020, the Cardiac segment market share increased from 4.52% to 4.72%; the Respiratory segment market share rose from 4.76% to 5.10%; the Anti-diabetic segment market share increased from 1.61% to 1.78%; and the Derma segment market share changed from 9.07% to 8.89%. Glenmark is ranked 2nd in the overall Dermatology market, 3rd in the overall Respiratory market and 6th in the cardiology market in India.

In April 2019, Glenmark announced the launch of its novel, patent protected and globally-researched sodium glucose co-transporter-2 (SGLT2) inhibitor Remogliflozin etabonate (Remogliflozin) in India. Glenmark is the first company in the world to launch Remogliflozin and the response from KOLs has been extremely positive. As per IQVIA March 2020 data, the sales for Remogliflozin franchise is tracking at Rs. 53 Mn. per month. Glenmark has attained 7.34 % market share in March 2020 in terms of value in the overall SGLT2 market in India. Glenmark has also launched the combination of Remogliflozin etabonate and Metformin Hydrochloride for adults with type 2 diabetes in India. The combination product has also received a good response from the market with sales crossing Rs. 10 Mn. in the month of March 2020 itself.

During the Fourth Quarter, Glenmark announced the partnership of its gynaecology division with Integrace Limited, a True North Company. Thus under this arrangement, the gynaecology business of India & Nepal was transferred to Integrace along with the employees of that division. The gynaecology business revenue is insignificant to the overall India business sales and is part of Glenmark's non-core business. The transaction was signed and closed in the Fourth Quarter of the financial year.

India – Glenmark Consumer Care Business

Glenmark Consumer Care business continued to maintain strong growth momentum of 31% in the quarter of this financial year and the business setting a new milestone of sales of Rs. 2038 Mn. in this financial year. This strong growth in the Fourth Quarter was led by Candid dusting powder with the highest ever growth of 38%. Candid powder added revenue of almost additional Rs. 90 Mn. in the fourth quarter. The new launch of Scalpe PRO also helped to drive the business with a growth of 42% in the fourth quarter. Modern trade channel led the growth agenda for the Consumer Care portfolio with 34% growth for the year.

During the quarter, the company announced that it has entered into an agreement with Hindustan Unilever Limited (HUL) for the divestment of its VWash brand and other extensions. Under this agreement, the brand and other trademarks, copyrights, know-how associated with Glenmark's VWash business will be transferred to HUL. Glenmark will receive an upfront payment and a certain percentage of sales for 3 years. No employees will be transferred as a part of this agreement. The transaction was completed on June 25, 2020.

USA

Glenmark Pharmaceuticals Inc., USA registered revenue from the sale of finished dosage formulations of Rs. 7,619.02 Mn (USD 105.11 Mn) for the quarter ended March 31, 2020 as against revenue of Rs. 7,696 Mn (USD 109.39 Mn) for the previous corresponding quarter, recording a de-growth of (1%).

In the fiscal year 2019-20, Glenmark was granted approval of 14 Abbreviated New Drug Applications (ANDA), comprised of 12 final approvals and 2 tentative approvals. Additionally, Glenmark was granted approval on a Prior Approval Supplement (PAS) to make an over-the-counter version of their Adapalene Gel, 0.1% available. Notable approvals include: Fulvestrant Injection, 250 mg/5 mL (the company's first injectable product), Pimecrolimus Cream, 1%, and Deferasirox Tablets for Oral Suspension, 125 mg, 250 mg and 500 mg. The Company filed a total of 8 ANDA applications with the

U.S. FDA throughout the fiscal year. The generic industry continues to be subdued with the overall generic topical dermatology market continuing to witness price erosion on a QoQ basis. On an YTD basis the overall generic topical dermatology market is estimated to have witnessed price erosion of around 20% for the entire financial year.

During this financial year, the US business was significantly impacted in terms of sales on account of three products viz. Mupirocin Cream, Atomoxetine hydrochloride & Calcipotriene cream. Further the sales was also impacted in the year due to Ranitidine.

Glenmark completed the successful launches of 16 products during fiscal year 2019-20, consisting of a mix of semi-solid preparations, delayed-and immediate-release oral solids, and hormone products. Notable launches include our first injectable product, Fulvestrant Injection, 250 mg/5 mL (as mentioned previously), an in-licensed product, Isradipine Capsules, where Glenmark quickly rose to be the market share leader and a re-introduction of Theophylline [Anhydrous] Extended-Release Tablets, where Glenmark answered a market need as one of the two available players exited the market.

In the fourth quarter of fiscal year 2019-20, Glenmark was granted final approval and launched Deferasirox Tablets for Oral Suspension, 125 mg, 250 mg and 500 mg. In addition, Glenmark launched the previously approved products Amlodipine and Olmesartan Medoxomil Tablets and Aspirin and Extended-Release Dipyridamole Capsules. The Company filed one ANDA application with the U.S. FDA, and plans to file an additional five applications in the forthcoming quarter.

Glenmark Canada filed one ANDS application and one NDS application with the Canadian Health Authorities this quarter.

Glenmark's marketing portfolio through March 31, 2020 consists of 165 generic products authorized for distribution in the U.S. market. The Company currently has 44 applications pending in various stages of the approval process with the US FDA, of which 24 are Paragraph IV applications.

Africa, Asia and CIS Region (ROW)

For the Fourth Quarter of FY 2019-20, revenue from Africa, Asia and CIS region was Rs.3,365.47 Mn (USD 46.54 Mn) as against Rs. 3,852.85 Mn (USD 54.88 Mn) for the previous corresponding quarter, recording degrowth of (12.65%).

In the fourth quarter of the financial year 2019-20, secondary sales for the Russian subsidiary showed 3.8% growth in value (vs same period last year). The Russia business continued to be subdued in the fourth quarter and the currency devaluation further impacted the business.

In the Dermatology segment in Russia, Glenmark ranks 11 amongst Dermatology companies present in the retail market on MAT March 2020 basis. The introductions under the Oflo umbrella i.e. Oflo nail lacquer and Oflo mycol cream & solution will further strengthen Company's position in this segment. Glenmark continues to invest into direct to consumer advertising, including the use of digital tools, of its key OTC brands in this therapy area. In the Respiratory space, Glenmark continues to secure a strong position and ranks 4 as per MAT March 2020 data amongst the companies present

on the expectorants market (retail segment) of the local pharmaceutical market. In addition to this, Glenmark launched Momate Rhino Advance (Mometasone + azelastive) metered nasal spray in OTC status for the treatment of seasonal and perennial allergic rhinitis in patients above 18 years of age, thus further strengthening its position in the respiratory (allergic rhinitis) segment and also OTC space. In addition to this, in February 2020 Glenmark launched its new montelukast + levocetirizine combination – Montlezir, tablets, thus expanding the portfolio of products. Furthermore, successful completion of Ryaltris™ clinical trials in Russia paves way for further expansion of the allergic rhinitis portfolio, once the regulatory approvals take place. Glenmark Ukraine recorded secondary sales growth of 33% in value for the Fourth Quarter of the financial year (vs. same period last year). The YTD March 2020 growth in value was 30% (vs same period last year).

The Asia region performance for the Fourth Quarter was average with secondary sales growth of only 1% reported for the region. Sales continued to remain subdued across all major Asian markets for Glenmark. The Africa region recorded secondary sales growth in the Fourth Quarter. This secondary sales growth was on account of the performance of the Kenya subsidiary.

Europe

Glenmark Europe's operations revenue for the Fourth Quarter of FY 2019-20 was at Rs. 4,115.68 Mn (USD 57.26 Mn) as against Rs. 3,184.07 Mn (USD 45.33 Mn) recording a growth of 29.26%.

Glenmark Europe operations performed well in the fourth quarter recording growth in excess of 20% in constant currency. The Western European business recorded growth of 23% in the quarter on account of the growth recorded by the German subsidiary. The Central Eastern European business also grew well in the Fourth Quarter. During the quarter, Glenmark Poland announced the partnership of its CNS portfolio to Neuraxpharm, a leading European pharma company. Following the transaction, the Glenmark CNS commercial team in Poland will join Neuraxpharm Polska's existing sales and marketing organisation to create a strong player in the Polish CNS market, with excellent access to psychiatrists, neurologists and pharmacies.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,768.73 Mn (USD 24.61 Mn) for the Fourth Quarter of FY 2019-20, as against Rs. 1,204.07 Mn (USD 17.14 Mn), recording an increase of 46.9 %. The strong growth rates recorded by the subsidiary was on account of the Brazil business which continues to benefit from the launch of the three respiratory products licensed from Novartis. The Mexico subsidiary also grew in excess of 30 % in constant currency.

During the quarter, the Brazilian subsidiary announced a partnership of a set of dermatology brands with a leading Brazilian pharmaceutical company Hypera. The transaction was signed in the fourth quarter of the financial year.

GPL Specialty/Innovative R&D Pipeline

Ryaltris™

Ryaltris™ (olopatadine hydrochloride and mometasone furoate) Nasal Spray is the company's respiratory pipeline asset and is currently under review with the U.S. Food and Drug Administration (FDA) as a treatment for seasonal allergic rhinitis in the USA.

During the fourth quarter, Glenmark and Hikma entered into an Exclusive Licensing Agreement for commercializing Ryaltris™ Seasonal Allergic Rhinitis Nasal Spray in the US . Under the terms of the agreement, Glenmark will be responsible for the continued development and regulatory approval of Ryaltris™ by the US FDA, while Hikma will be responsible for the commercialization of Ryaltris™ in the US . Glenmark will receive an upfront payment now and on regulatory approval. Glenmark will also receive commercial milestone payments as well as royalties from Hikma for Ryaltris™ . Besides the US deal, Glenmark has already signed licensing deals for commercializing Ryaltris™ in China, Australia, New Zealand and South Korea

Glenmark is also working to close a partnership deal for Ryaltris™ in various other markets including the EU. The company has already filed an application for Ryaltris™ approval in the European Union.

During the first quarter of FY 2019-20, the USFDA issued a Complete Response Letter (CRL) pertaining to the New Drug Application(NDA) for Ryaltris™. We continue to work with the agency to resolve the issues raised in the CRL. The CRL response is currently on track for submission shortly. We are in communication with the FDA and all deficiencies, except the facility clearance, are minor in nature and have been already addressed

During the third quarter of the financial year, Glenmark announced that its partner Seqirus Pty. Ltd. (Seqirus) has received marketing approval for Ryaltris® from the Therapeutic Goods Administration (TGA), Australia. We have already despatched launch quantities to Seqirus in this month and they are planning for the launch of Ryaltris™ in Australia in Q2 FY 2021. Recently the company's partner in South Korea Yuhan Corporation also received regulatory approval which paves the way for the launch of Ryaltris in South Korea

Further in the last few months Ryaltris™ has been approved in Cambodia, Uzbekistan Namibia and South Africa. Also Ryaltris™ clinical trials in Russia has been completed and the subsidiary will shortly seek regulatory approval from the regulator.

Note: All brand names and trademarks are the property of their respective owners.

GBR 310

During FY 2018-19, Glenmark announced results from a Phase 1 study that suggest similarity in pharmacokinetic, pharmacodynamic, safety and immunogenicity profiles between GBR 310, and the reference product, omalizumab, marketed in the US under the brand name Xolair®. The Company is in discussions with potential partners and is targeting to conclude a deal before initiating Phase 3 studies.

GRC 39815 (RORyt inhibitor)

GRC 39815 is a NCE currently being evaluated as an inhaled compound for the possible treatment of Chronic Obstructive Pulmonary Disorder (COPD). It is an inhibitor of the Retinoid-related Orphan Receptor gamma t (RORyt). The compound is currently in pre-clinical development and the Company plans to initiate a Phase 1 study shortly.

GLENMARK LIFE SCIENCES LTD. (GLS)

Glenmark Life Sciences primarily includes manufacturing and marketing of Active Pharmaceutical Ingredient (API) products across all major markets globally. It also includes captive sales (i.e. use of API by GPL for its own formulations).

For the Fourth Quarter of FY 2019-20, external sales for Glenmark Life Sciences was at Rs. 2,613.79 Mn (USD 36.12 Mn) as against Rs. 2,487.77 Mn (USD 35.39 Mn), recording growth of 5.07% over the corresponding period last year.

Once again the US and Emerging markets led the growth in the Fourth Quarter, with both regions growing in excess of 30% in the quarter. In the US market the growth was led by Aprepitant. GLS continues to look at opportunities with various partners globally and has been seeding multiple products across various regions. During the quarter, the company filed two US DMF.

For the entire year, external sales of Glenmark Life Sciences recorded revenue of Rs. 10,239.17 Mn (USD 144.66 Mn) as against Rs. 9,493.11 Mn (USD 136.08 Mn) in the previous financial year, recording growth of 7.86% over the corresponding period last year.

ICHNOS Sciences

For the nine months ended Dec 31, 2020, Glenmark invested Rs 5,943 Mn (USD 85.03 Mn) and in the fourth quarter of the financial year, the company invested approx. Rs 2,250 Mn (USD 32 Mn). Thus for the entire financial year, Glenmark invested Rs. 8,193 Mn (USD 115.73 Mn) in Ichnos Sciences.

Ichnos Sciences initiated the process to raise capital in the US in this current month to fund the development of its pipeline and for future growth plans.

For further updates on the pipeline and the organisation, please log on to www.ichnosciences.com. The pipeline update for the fourth quarter is published.

Update On Chief Commercial Officer for Glenmark Pharmaceuticals Limited

Glenmark recently announced the appointment of Mr. Robert Crockart as Chief Commercial Officer, Glenmark Pharmaceuticals Limited. Mr. Crockart will be based at Glenmark's Head Office in Mumbai and report directly to the Chairman & Managing Director. Mr. Crockart comes with over 26 years of end to end experience across various industries including the Pharmaceutical Industry, Consumer Health, Retail, Pharmaceutical Wholesale and Outsourcing. He has successfully operated and transformed businesses for growth across multiple geographies in Europe, Asia, Latin America, Middle East and Africa. Prior to Glenmark, Mr. Crockart was Divisional Vice President (DVP) – Asia

Pacific for Abbott. He was instrumental in expanding the MEAP region for Abbott year on year over 5 years as DVP. He also established the EPD Sales Strategy globally, across all Emerging Markets contributing to its consistent over achievements. All the business heads at Glenmark will report into Mr. Crockart. He will be responsible for the entire formulations business of Glenmark Pharmaceuticals Limited.

Disclaimer

This document has been prepared by Glenmark Pharmaceuticals Ltd. The information, statements and analysis made in this document describing company's objectives, projections and estimates are forward looking statements and progressive within the meaning of applicable Security Laws and Regulations. The analysis contained herein is based on numerous assumptions. Actual results may vary from those expressed or implied depending upon economic conditions, government policies and other incidental factors. No representation or warranty, either expressed or implied, is provided in relation to this presentation. This presentation should not be regarded by recipients as a substitute for the exercise of their own judgment.

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ICHNOS SCIENCES INC.

JUNE 2020 UPDATE

Ichnos Sciences is shifting the way the world thinks about innovation in medicine through its research and development of potentially transformative treatments in oncology and autoimmune disease. The Company, with headquarters in the NYC area and discovery and manufacturing at two locations in Switzerland, has strong capabilities in the research and development of new biological entities (NBE). Ichnos is also engaged in the discovery of new chemical entities (NCE) to treat cancer through an agreement with Glenmark Pharmaceuticals, Ltd. for work being conducted at their research facility in the Mumbai, India area.

Ichnos currently has four molecules in clinical development: two in oncology, one in autoimmune disease, and one in pain. With a patented BEAT[®] technology platform¹ for biologic drugs, along with drug pioneering teams across locations, Ichnos Sciences has a mission to provide breakthrough, curative therapies that will hopefully extend and improve lives, writing a new chapter in healthcare.

Officially launched on 15 October 2019, Ichnos has an experienced executive leadership team and board of directors. The Company is a subsidiary of Glenmark Holding SA, which is funding operating expenses while additional investors are secured during CY 2020 and beyond.

HIGHLIGHTS

Over the past quarter, Ichnos has completed the steps required to form an independent company, including the transition of colleagues in the United States and Switzerland to Ichnos Sciences. Due to difficulties encountered in obtaining approval from the authorities in India, Glenmark employees who were previously expected to transfer to Ichnos will remain with Glenmark. These individuals will continue to do work for Ichnos on NCE for the treatment of cancer through an agreement between the two companies.

Both clinical- and preclinical-stage assets have continued to progress, with top-line results for the first part of a Phase 2b study of ISB 830 available this quarter. Recruitment for the second part of this study, as well as for other Ichnos clinical studies, has been paused due to the COVID-19 pandemic. Our Business Continuity Plan (BCP) has enabled us to continue preclinical work through the pandemic, and we are on track to initiate IND-enabling studies for a number of assets later this calendar year.

¹ Bispecific Engagement by Antibodies based on the T cell receptor



UPDATE ON ICHNOS PIPELINE OF STAGE DRUGS

MOLECULE MECHANISM/CLASS	POTENTIAL INDICATIONS	PHASE	STATUS (DATES ARE IN CALENDAR YEAR)
AUTOIMMUNE DISEASE			
ISB 830 OX40 Antagonist	Atopic Dermatitis	Phase 2b	Recruitment in Part 1 of this randomized double-blind placebo-controlled Phase 2b study is complete. Top-line results (Part 1) showed statistically significant improvement in percent change from baseline in Eczema Area and Severity Index (EASI) for the highest dose tested versus placebo. Improvement in the secondary efficacy endpoints was not statistically significant versus placebo. Enrollment in Part 2 of the study, which is assessing effects of a higher dose versus placebo, has been paused due to the COVID-19 pandemic. Results expected in first half 2021, pending any impact of the pandemic on study progress.
	Rheumatoid Arthritis	Phase 2b	Planning underway. Study start dependent on impact of pandemic.
PAIN			
ISC 17536 TRPA1 Antagonist ²	Painful Diabetic Peripheral Neuropathy	Phase 2a	Phase 2a study was previously completed. Primary endpoint was not met for the overall study population, but a statistically significant reduction in pain was seen compared to placebo in a prespecified subgroup of patients with preserved small nerve fiber function. Additional nonclinical studies have started this year.
ONCOLOGY			
ISB 1302 HER2 x CD3 Bispecific Antibody	Breast Cancer	Phase 1/2	Enrolling
ISB 1342 CD38 x CD3 Bispecific Antibody	Multiple Myeloma	Phase 1	Enrolling

² Transient receptor potential ankyrin-1 (TRPA1) inhibitor



AUTOIMMUNE DISEASE

ISB 830 (OX40 ANTAGONIST)

- Recruitment in Part 1 of the Phase 2b study of ISB 830 (anti-OX40 monoclonal antibody) is complete and top-line results are available. This is a randomized double-blind study in two parts. Part 1 assessed three doses and dosing schedules versus placebo in 313 adult patients with moderate-to-severe atopic dermatitis (AD) across study sites in the US, Canada, Germany, Czech Republic, and Poland.
- In Part 1, the highest dose of ISB 830 tested resulted in a statistically significant improvement in percent change from baseline of the Eczema Area and Severity Index (EASI) score compared to placebo at week 16.
- Numerical improvement was seen in the secondary endpoints of EASI-75³ and IGA⁴, but the differences were not statistically significantly different from placebo.
- No deaths, malignancies, or thromboembolic events were reported, and the most commonly reported serious adverse event was atopic dermatitis (1.3% vs 1.3% for placebo).
- The most commonly reported (>5%) treatment-emergent adverse events for ISB 830 were: atopic dermatitis (21.2% vs 22.5% for placebo); nasopharyngitis (8.2% vs 8.8% for placebo); upper respiratory tract infection (7.4% vs 5.0% for placebo); and headache (5.6% vs 10.0% for placebo).
- Randomization of an additional 156 patients is underway into Part 2 of the AD study, which is assessing the effects of a higher dose versus placebo. Recruitment has been paused due to the COVID-19 pandemic, and top-line results of Part 2 are expected in the first half of CY 2021, pending any impact of the pandemic on study progress.
- In addition, a US IND to conduct studies of ISB 830 in additional indications, including Rheumatoid Arthritis (RA), is now active. Planning for a Phase 2b study in RA is underway, with start date dependent on impact of the pandemic.

PAIN

ISC 17536 (TRPA1 ANTAGONIST)

- A Phase 2a proof-of-concept (PoC) study of the oral transient receptor potential ankyrin-1 (TRPA1) inhibitor, ISC 17536, was previously completed in Europe and India in adult patients with painful diabetic peripheral neuropathy (DPN).

³ Proportion of patients with $\geq 75\%$ improvement in EASI score from baseline to Week 16

⁴ Proportion of patients with Investigator Global Assessment of clear or almost clear (0 or 1) and ≥ 2 point reduction from baseline at Week 16

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- While the primary endpoint of change from baseline to week 4 in average pain intensity was not met in the overall study population, a statistically significant reduction in pain was seen compared to placebo in the prespecified subgroup of subjects with preserved small nerve fiber function.
- At a Type C meeting with FDA in March 2020, agreement was reached regarding the nonclinical plan to enable a randomized, double-blind, placebo-controlled, Phase 2b, dose-range finding study for painful DPN. These nonclinical studies are ongoing/planned, and a formulation study in healthy volunteers is expected to start in the first half of CY 2021.

ONCOLOGY

ISB 1302 (HER2 X CD3 BISPECIFIC ANTIBODY)

- A Phase 1/2, first-in-human study of ISB 1302 to determine the maximum tolerated dose (MTD) with bi-weekly dosing in patients with HER2-positive cancers completed enrollment in the US and Germany in May 2019.
- A Phase 1/2 study of ISB 1302 to evaluate a weekly dosing regimen is ongoing.

ISB 1342 (CD38 X CD3 BISPECIFIC ANTIBODY)

- A Phase 1, first-in-human study of ISB 1342 to determine the MTD in a bi-weekly dosing regimen in patients with refractory multiple myeloma was closed to further enrollment in March 2020 following evaluation of safety/efficacy and PK/PD of 11 cohorts.
- A Phase 1 study of ISB 1342 to evaluate a weekly dosing regimen is ongoing.

UPDATE ON PIPELINE OF ICHNOS PRECLINICAL NBE CANDIDATES, AND NCE PRECLINICAL CANDIDATES, UNDER AGREEMENT WITH GLENMARK

Ichnos will continue to leverage its capabilities in NBEs, particularly through the BEAT[®] platform, and will continue to advance NCEs in oncology through an agreement with Glenmark. The Company is planning to advance to IND-enabling studies for a number of candidates in 2020 and beyond.

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**NEW BIOLOGIC ENTITY (NBE)
AND NEW CHEMICAL ENTITY (NCE) CANDIDATES**

CATEGORY / CANDIDATE	PRECLINICAL	IND-ENABLING STUDIES	
		CY 2020	CY 2021
ONCOLOGY NBE			
ISB 1908	T-cell engager	2H 2020	
ISB 1909	T-cell engager		1H 2021
ISB 1442	Innate immune engager	2H 2020	
AUTOIMMUNE DISEASE NBE			
ISB 880	Targeted anti-inflammatory therapy	2H 2020	
ONCOLOGY NCE			
ISC XXXXX	HPK1 inhibitor	2H 2020	

Ichnos continues to advance additional biologic and small molecule candidates with its discovery teams in Switzerland and through an agreement with Glenmark, respectively.

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**STRATEGIC PRIORITIES FOR BIOLOGICS
DISCOVERY RESEARCH IN IMMUNO-ONCOLOGY**

**FOCUS ON DISEASE-CENTRIC APPROACH AND LEVERAGE BEAT® ANTIBODY ENGINEERING PLATFORM
TO DELIVER FIRST-IN-CLASS CANDIDATES**

MULTIPLE MYELOMA (MM)	HEMATOLOGICAL MALIGNANCIES	SOLID TUMORS
<ul style="list-style-type: none">• Optimize molecular attributes of ISB 1342 (CD 38 x CD3) T-cell engager• Deliver a competitive MM portfolio by advancing next wave of T-cell engagers and innate immune engagers (e.g., NK, macrophages)	<ul style="list-style-type: none">• Accelerate delivery of innovative concepts by leveraging trispecific T-cell and innate immune engagers (e.g., NK, macrophages)	<ul style="list-style-type: none">• Optimize molecular attributes of ISB 1302 (HER2 x CD3) T-cell engager