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# ICHNOS SCIENCES INC.

# November 2019 Update

Ichnos Sciences is shifting the way the world thinks about innovation in medicine through its transformative treatments in oncology, autoimmune disease and pain. The Company, with headquarters in Paramus, NJ, and facilities in Switzerland and India, has strong capabilities in the research and development of new biological entities (NBE) and new chemical entities (NCE). Ichnos currently has five molecules in clinical development for multiple indications: two in oncology, one in autoimmune disease and two 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.

Ichnos Sciences, which officially launched on 15 October 2019, is in the process of obtaining all the necessary statutory, legal, corporate and regulatory approvals for completion of the spin-off from Glenmark Holding SA, which is expected to occur in the first quarter of calendar year 2020. Ichnos' operations are currently funded through investments by Glenmark, and securing additional investors will be a key initiative in 2020.

## Highlights

Ichnos recently notified regulatory authorities that the Company name has been changed from Glenmark Pharmaceuticals, SA to Ichnos Sciences SA. Additionally, the naming convention for drug candidates has been changed, and assets that were formerly identified as GBR and GRC will now be identified as ISB (for biologics) and ISC (for small molecules), respectively. Notification of these changes to external parties is underway.

<sup>&</sup>lt;sup>1</sup> Bispecific Engagement by Antibodies based on the T cell receptor

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# **Update on Ichnos Pipeline of Clinical Stage Drugs**

Molecule Mechanism/ Class	Potential Indications	Phase	Status (Dates are in Calendar Year)
Autoimmune Disease			
ISB 830 OX40 Antagonist	Atopic Dermatitis	Phase 2b	Part 1 of this randomized double-blind placebo-controlled Phase 2b study is fully enrolled. Top-line results(Part 1) in first half of 2020. Part 2 is enrolling
	Rheumatoid Arthritis	Phase 2b	To start in 2020
	Systemic Lupus Erythematosus	Phase 2b	Timing of study start to be determined
Pain			
ISC 27864 mPGES-1 Inhibitor	Osteoarthritic Pain	Phase 2b	Fully enrolled. Top-line results of this randomized double-blind placebo-controlled study in first half of 2020
ISC 17536 TRPA1 Antagonist	Painful Diabetic Peripheral Neuropathy	Phase 2a	Phase 2a study completed. Additional studies to start in 2020
Oncology			
ISB 1302 HER2xCD3 Bispecific Antibody	Breast Cancer	Phase 1a/1b	Currently enrolling
ISB 1342 CD38xCD3 Bispecific Antibody	Multiple Myeloma	Phase 1a/1b	Currently enrolling

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#### **Autoimmune Disease**

#### ISB 830 (OX40 Antagonist)

- Part 1 of the Phase 2b study of ISB 830 (anti-OX40 monoclonal antibody) has been fully enrolled. This is a randomized double-blind study assessing three doses and dosing schedules versus placebo in 312 adult patients with moderate-to-severe atopic dermatitis (AD) across study sites in the US. Canada, Germany, Czech Republic and Poland. Top-line results of Part 1 of the Phase 2b study in AD are expected to be available in the first half of 2020.
- Randomization of an additional cohort of 156 patients is underway into Part 2 of the AD study (high-dose arm vs placebo). Top-line results of Part 2 are expected in the second half of 2020.
- In addition, a Phase 2b study to evaluate the safety and efficacy of ISB 830 for the treatment of adults with Rheumatoid Arthritis is in preparation, with a target start date in the first half of 2020.
- Studies to evaluate the safety and efficacy of ISB 830 in Systemic Lupus Erythematosus and other Autoimmune Diseases are under consideration.

#### Pain

#### ISC 27864 (mPGES-1 inhibitor)

- ISC 27864 is a non-opioid, selective, and orally bioavailable inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1). Enrollment was recently completed in a randomized double-blind placebo-controlled Phase 2b study of three doses administered once-daily in 624 patients in India with osteoarthritic pain of the knee or hip.
- Top-line results of the Phase 2b study are expected to be available in the first half of 2020.
- Additional indications are under consideration.

#### ISC 17536 (TRPA1 antagonist)

• A Phase 2a proof of concept 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).

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- ISC 17536 is on clinical hold since 2015 as a result of preclinical (nonclinical) questions from the FDA. Nonclinical studies have been resumed and Ichnos is now in the process of addressing the regulatory questions to lift the clinical hold.
- The Company is planning to initiate a Phase 2b dose-range finding study of ISC 17536 in adults with painful DPN in 2020.
- Additional indications are under consideration.

### Oncology

#### ISB 1302 (HER2xCD3 bispecific antibody)

- A Phase 1, 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.
- The Company recently initiated a Phase 1 study of ISB 1302 to evaluate a weekly dosing regimen.

## ISB 1342 (CD38xCD3 bispecific antibody)

- Enrollment in 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 is ongoing in the US. Cohorts 1-10 have been completed, and the study continues with the enrollment of patients into Cohort 11.
- The Company has amended the protocol to include a weekly dosing regimen in the current study. Cohort 1 enrollment into the weekly dosing regimen has been completed.

### **Update on Ichnos Pipeline of Preclinical Candidates**

Ichnos will continue to leverage its capabilities in NCEs and NBEs, particularly through the BEAT® platform, and is planning to advance additional small molecule and biologic candidates, including a MAP4K1 inhibitor, in 2020 and beyond.