

February 12, 2018



## **Roivant and Poxel Announce Strategic Agreement for Development and Commercialization of Imeglimin in the U.S., Europe, and Additional Countries Worldwide**

- **Poxel to receive upfront payment of \$35 million (approximately €28 million), potential future development and regulatory milestone payments and sales-based payments of up to \$600 million (approximately €486 million), and double-digit royalties on net sales**
- **Roivant to concurrently invest \$15 million (approximately €12 million) in Poxel through subscription to newly-issued ordinary shares at €8.5 per share**
- **Poxel to contribute \$25 million (approximately €20 million) to the development program**
- **Roivant will be responsible for imeglimin's development and commercialization in the U.S., Europe, and other countries outside of Poxel's partnership with Sumitomo Dainippon Pharma**
- **Poxel to hold investor call today at 1 pm ET (7 pm CET)**

BASEL, Switzerland & LYON, France--(BUSINESS WIRE)-- [Roivant Sciences](#), a global healthcare company focused on realizing the full value of promising biomedical research, and [POXEL SA](#) (Euronext: POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for metabolic disorders including type 2 diabetes, today announced the signing of a strategic development and license agreement for imeglimin, an investigational oral therapy which has been developed by Poxel for the potential treatment of type 2 diabetes, in the U.S., Europe, and all other countries not covered by Poxel's existing agreement in East and Southeast Asia.<sup>1</sup> This partnership enables Roivant to add an innovative late-stage development program to its pipeline and Poxel gains a strategic development and licensing agreement for imeglimin beyond the company's partnership with Sumitomo Dainippon Pharma.

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Under the terms of the agreement, Poxel is entitled to receive an upfront payment of \$35

million (approximately €28 million) and Roivant will invest \$15 million (approximately €12 million) in Poxel through a subscription to 1,431,399 newly-issued ordinary shares at €8.5 per share. Poxel is entitled to receive potential future development and regulatory milestone payments and sales-based payments of up to \$600 million (approximately €486 million) subject to the successful clinical development and commercialization of imeglimin. Furthermore, after launch Poxel will be entitled to double-digit royalties on net sales. Roivant will be responsible for development and commercialization costs and Poxel will contribute \$25 million (approximately €20 million) to the development program. The parties will decide on a potential co-promotion prior to commercialization.

“We are very pleased to partner with Roivant, an emerging leader in biopharma with proven commitment to developing innovative therapies in major disease areas. Roivant’s vision complements Poxel’s strategy of bringing novel treatments for type 2 diabetes and other metabolic disorders to patients,” said Thomas Kuhn, CEO of Poxel. “This is a significant milestone for Poxel and for the development of imeglimin in the U.S., Europe, and other countries outside of the Asian markets where we have already partnered with Sumitomo Dainippon Pharma. The imeglimin Phase 3 TIMES type 2 diabetes program in Japan is underway with a target Japanese New Drug Application submission in 2020, and imeglimin is ready to advance into late-stage development in the U.S. and Europe. 2018 will be a transformative year for Poxel as we advance the TIMES program in Japan, collaborate with Roivant on imeglimin, and increase our focus on our earlier-stage pipeline.”

“We are pleased to have reached this agreement with Poxel as we continue our strategy of in-licensing late-stage development candidates in underserved therapeutic areas,” said Vivek Ramaswamy, Founder and CEO of Roivant Sciences. “This agreement represents the beginning of our focus on metabolic diseases and imeglimin, with its compelling and consistent data, will be a cornerstone program. We are looking forward to rapidly advancing its development.”

Activities in 2018 to support initiation of the Phase 3 program will include differentiation studies to confirm imeglimin’s potential in sensitive patient populations, such as those with chronic kidney disease, as well as manufacturing of the drug product for use in the Phase 3 program. The goal is to initiate the Phase 3 program in the U.S. and Europe in 2019.

Imeglimin has completed Phase 1 and Phase 2 development in 18 clinical studies involving over 1,200 subjects with type 2 diabetes in the U.S., Europe, and Japan, and met its primary and secondary endpoints, including a statistically significant decrease of HbA1c and fasting plasma glucose versus placebo, with a favorable side effect profile. For more information about imeglimin clinical studies, please visit [www.poxelpharma.com](http://www.poxelpharma.com).

Poxel will host an investor conference call today to discuss this partnership at 1 pm Eastern Time (7 pm Central European Time). To participate in the call, please use the dial-in numbers below.

France: +33 (0)1 70 807 153  
UK: +44 (0) 20 3107 0289  
US: +1 (877) 293 6124

Conference ID: **8391409**

A recording of the conference call will be available two hours after the call's completion for at least 30 days. To access the recording, use the dial-in below.

Replay Number:

US : +1 (855) 859-2056

Outside US: +1 (404) 537-3406

Access code: **8391409**

## **About Imeglimin**

Imeglimin is the first clinical candidate in a new chemical class of oral agents called the Glimins by the World Health Organization. Imeglimin has a unique mechanism of action (MOA) that targets mitochondrial bioenergetics and acts on the three key organs which play an important role in the current anti-diabetic treatment paradigm: the liver, muscles, and the pancreas<sup>2</sup>. Studies conducted to date have suggested potential glucose lowering benefits through increased insulin secretion in response to glucose<sup>3</sup>, improved insulin sensitivity<sup>4</sup>, and suppression of gluconeogenesis<sup>2</sup>. Imeglimin's MOA also has the potential to prevent endothelial and diastolic dysfunction<sup>5,6,7</sup>, and to provide protective effects on beta-cell survival and function<sup>8</sup>. Poxel plans to publish preclinical and clinical data on imeglimin and to present findings at multiple scientific and medical congresses in 2018.

## **About Poxel SA**

Poxel uses its development expertise in metabolism to advance a pipeline of drug candidates focused on the treatment of metabolic disorders, including type 2 diabetes. We have successfully completed our Phase 2 clinical program for our first-in-class lead product, imeglimin, which targets mitochondrial dysfunction, in the U.S., Europe and Japan, and the Phase 3 Trials of **Im**eglimin for **E**fficacy and **S**afety (TIMES) program in Japan is underway. Our second program, PXL770, a direct adenosine monophosphate-activated protein kinase (AMPK) activator, is completing Phase 1 development. Based on this central metabolic role, targeting AMPK offers the opportunity to pursue a wide range of indications to treat chronic metabolic diseases, including diseases that affect the liver, such as non-alcoholic steatohepatitis (NASH). We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, [www.poxelpharma.com](http://www.poxelpharma.com))

## **About Roivant Sciences**

Roivant is dedicated to transformative innovation in healthcare. Roivant focuses on realizing the full potential of promising biomedical research by developing and commercializing novel therapies across diverse therapeutic areas. Roivant partners with innovative biopharmaceutical companies and academic institutions to ensure that important medicines are rapidly developed and delivered to patients.

Roivant advances its drug pipeline through wholly- or majority-owned subsidiary companies, including Axovant (neurology), Myovant (women's health and endocrine diseases), Dermavant (dermatology), Enzyvant (rare diseases), and Urovant (urology). Roivant also pursues its mission by incubating and launching innovative healthcare companies operating outside of traditional biopharmaceutical development. Roivant's long-range mission is to reduce the time and cost of developing and delivering new medicines for patients. For more

information, please visit [www.roivant.com](http://www.roivant.com).

## **Forward-Looking Statement**

All statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results or performance to be materially different from the expected results or performance expressed or implied by such forward-looking statements.

1. The Poxel and Roivant agreement includes all countries other than those covered under the Poxel and Sumitomo Dainippon Pharma agreement, which includes Japan, China, the Republic of Korea, Taiwan, Indonesia, Vietnam, Thailand, Malaysia, The Philippines, Singapore, Republic of the Union of Myanmar, Kingdom of Cambodia, and Lao People's Democratic Republic.
2. Fouqueray et al., J Diabetes Metab 2011, 2:4.
3. Pacini G et al., Diabetes Obes Metab. 2015;17:541-5.
4. Vial et al., Diabetes, 2015;64:2254-2264.
5. Dettelle et al. Cell Death Discovery, 2016; 2,15072.
6. Poster #717, European Association for the Study of Diabetes, 12th–16th September 2016, Munich, Germany.
7. Poster #2054, American Diabetes Association, 9th–13th June 2017, San Diego, USA.
8. Poster #00084 World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease, 1st–3rd December 2016, Los Angeles, USA.

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