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Poxel Announces Positive Results From the First Stage of the Ongoing PXL770 Phase 1 Trial

PXL770 is a direct AMPK activator; a drug candidate in the new class of “exercise mimetic”

LYON, France--(BUSINESS WIRE)-- Poxel SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative drugs to treat type 2 diabetes, today announced positive results from the single ascending dose stage, which is the first stage of the ongoing PXL770 Phase 1 clinical trial. PXL770 is a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, a key enzyme in energy metabolism acting as an energy sensor regulating glucose and lipid levels. AMPK activation is considered to mimic the effects of long-term exercise and plays an important role in diabetes management, especially for patients with cardiovascular risk factors.

In the first part of the study, safety, tolerability and pharmacokinetics of six single ascending oral doses of PXL770 were assessed in 64 healthy male subjects. Overall, the results indicate that PXL770 exhibits a favorable safety and tolerability profile with no serious adverse events reported nor safety signals. Pharmacokinetic assessment showed that PXL770 plasma exposure (Cmax and AUC) increased in a dose dependent manner following oral administration with moderate inter-individual variability. The second part of the trial is on track and will assess safety, tolerability, pharmacokinetics and target engagement of multiple ascending doses.

“Poxel continues to solidify its leadership position in the type 2 diabetes therapeutic area with two programs successfully advancing in clinical development. We are very pleased with the first clinical results and look forward to continuing to move this program forward as well as Imeglimin, which is in late stage clinical development,” said Thomas Kuhn, CEO of Poxel. “PXL770 is a first-in-class product with a unique mode of action which we believe targets an important mechanism for the treatment of type 2 diabetes as well as other metabolic disorders.”

Poxel presented the first preclinical data on PXL770 at the World Congress on Insulin Resistance, Diabetes and Cardiovascular Diseases in Los Angeles last November, demonstrating that PXL770 significantly improves glucose tolerance, lipid profile as well as liver weight in a type 2 diabetes mouse model. Together, the results highlight the potential of PXL770 as a novel oral agent for the treatment of type 2 diabetic patients with added benefits on lipid abnormalities.

About PXL770

PXL770 directly activates adenosine monophosphate-activated protein kinase (AMPK), an enzyme that acts as an energy sensor and regulator, maintaining cellular homeostasis, thus playing an important role in the management of diabetes. In addition to its anti-diabetic properties, PXL770 has the potential to treat lipid-related abnormalities, which are present in a vast majority of diabetic patients and are the cause of cardiovascular incidents among this population, as well as other metabolic disorders.

About Poxel

Poxel uses its development expertise in metabolism to advance a pipeline of drug candidates focused on the treatment of type 2 diabetes. We have successfully completed our Phase 2 trials for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S. and EU and have entered Phase 2b clinical development in Japanese patients. We are advancing our second program, PXL770, a direct AMPK activator, which is in Phase 1 development. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxel.com)

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Poxel SA
Jonae Barnes, + 1 617-818-2985
Senior Vice President, Investor Relations and Public Relations
jonae.barnes@poxelpharma.com
or
Investor relations / Media - EU/US
MacDougall Biomedical Communications
Gretchen Schweitzer or Stephanie May
+ 49 89 2424 3494 or + 49 175 571 1562
smay@macbiocom.com
or
Investor relations / Media – France
NewCap
Florent Alba/Nicolas Mérigeau
+ 33 1 44 71 98 55
poxel@newcap.fr

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