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Poxel Announces PXL770 Advances into a Phase 1b Multiple Ascending Dose Trial

- PXL770 is a direct AMPK activator; a central regulator of multiple metabolic pathways that provides the opportunity to treat a wide range of metabolic diseases

LYON, France--(BUSINESS WIRE)-- POXEL SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for metabolic disorders, including type 2 diabetes, announced today that it has initiated a Phase 1b multiple ascending dose (MAD) trial for PXL770 and subjects have been dosed. The MAD trial will include up to 76 subjects and evaluate the safety, tolerability and pharmacokinetics of PXL770 in at least four dose groups. Completion of the MAD trial is anticipated in early 2018.

PXL770 is a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator. AMPK plays a key role as a master regulator of cellular energy, which turns on pathways that replenish energy and turns off pathways that consume energy, leading to the control of lipid metabolism, glucose homeostasis and inflammation. Based on this central metabolic role, targeting AMPK offers the opportunity to pursue a wide range of indications to treat chronic metabolic diseases,[1] including diseases that affect the liver, such as non-alcoholic steatohepatisis (NASH), as well as type 2 diabetes and diabetes-related complications, such as diabetic nephropathy.

“Through its unique mechanism of action that directly activates AMPK, PXL770 acts on a very important biological target that has the potential to treat numerous chronic metabolic diseases. Many of these diseases could provide Poxel with the opportunity to conduct development programs targeting several different indications,” said Thomas Kuhn, CEO of Poxel. “In parallel, we are currently evaluating the potential to study PXL770 in several of these diseases while advancing the Phase1b clinical development program. We anticipate that a proof-of-concept program for PXL770 could begin mid-2018.”

In the PXL770 Phase 1a study, safety, tolerability and pharmacokinetics of six single ascending oral doses of PXL770 were assessed in 64 healthy male subjects. The results demonstrated that PXL770 exhibited 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.

At the European Association for the Study of Diabetes meeting in 2016, Poxel presented PXL770 data showing its effect on *de novo* lipid synthesis and on weight and fat mass loss

in an animal model of diabetes and obesity. For additional information, please visit http://www.poxelpharma.com/en_us/product-pipeline/posters.

About PXL770
PXL770 is a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator. AMPK is a central regulator of multiple metabolic pathways leading to the control of lipid metabolism, glucose homeostasis and inflammation. Based on this central 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 NASH, as well as type 2 diabetes and diabetes-related complications, such as diabetic nephropathy.

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., EU and Japan. Our second program, PXL770, a direct AMPK activator, is in Phase 1 development. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxel.com)

[1] Source: Srivastava, R. A et al., (2012) Journal of Lipids Research 53, 2490- 2514

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