



KEY HIGHLIGHTS



Well diversified mid-to-late stage pipeline with first-in-class drug candidates



A highly experienced management team with extensive metabolic expertise



Key partnership with type-2-diabetes market leader in Japan for its most advanced clinical program, Imeglimin



Two differentiated programs for NASH (PXL770 / PXL065), a large and growing disease worldwide



Cash and cash equivalents were EUR 32.8 million (USD 38.4 million) as of March 31, 2021, sufficient to fund operations through 2022

CONTACTS

- Corporate headquarters in Lyon, France
- Poxel also has subsidiaries in Tokyo, Japan, and in the Boston, Massachusetts area

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ABOUT POXEL

Poxel is a **dynamic biopharmaceutical company** that uses its extensive expertise in developing **innovative drugs for metabolic diseases**, with a focus on **type 2 diabetes**, **non-alcoholic steatohepatitis (NASH)**, and selected rare inherited disorders including adrenoleukodystrophy. In its mid-to-late stage pipeline, the Company is currently advancing three drug candidates; several earlier-stage opportunities are also under way.







Imeglimin, Poxel's first-in-class lead drug candidate, targets mitochondrial dysfunction. Poxel has a strategic partnership with **Sumitomo Dainippon Pharma** for Imeglimin in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries. A Japanese new drug application (J-NDA) is under review by the Pharmaceuticals and Medical Devices Agency (PMDA) to request approval for the manufacturing and marketing of Imeglimin for the treatment of type 2 diabetes.

PXL770, a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is being developed for the treatment of NASH. After successfully completing a Phase 2a proof-of-concept trial, which met its primary endpoint and study objectives, Poxel plans to initiate a Phase 2b program in the second half of 2021. PXL770 also has the potential to treat additional metabolic diseases.

PXL065 is the R-enantiomer of pioglitazone, stabilized by deuterium, and targets non-genomic (non-PPAR γ) pathways. It is being developed for the treatment of NASH, and is currently being studied in a streamlined Phase 2 study with biopsy proven NASH patients with results anticipated in mid-2022.

Poxel also has additional earlier-stage programs from its AMPK activator and deuterated TZD platforms targeting chronic and rare metabolic diseases.

A WELL-DIVERSIFIED METABOLIC PIPELINE

Indication	MOA	Discovery/PC	PH 1	PH 2	PH 3	NDA review	Partner/ Rights	Upcoming Milestones
Type 2 Diabetes (T2D)								
Imeglimin Japan / Asia ¹	T2D	MRC Modulator						Target product launch in 2021 ² in Japan
Imeglimin US / EU / Other	T2D with CKD stages 3b/4	MRC Modulator						Exploring options to move the program forward into Phase 3
NASH								
PXL770	NASH with T2DM	AMPK Activator						Initiate Phase 2b study in 2H 2021
PXL065	NASH	MPC Inhibitor						Phase 2 results mid-2022 505(b)(2) pathway
PXL007 (EYP001)	Hepatitis B / NASH	FXR Agonist						Complete Ph 2a program by Enyo Pharma mid-2021
Other Chronic and Rare Metabolic Indications								
Next-Gen AMPK	ALD/AMN, ADPKD, CKD, other	AMPK Activator						Complete PC studies in 2021 Select lead candidate(s)
Next-Gen D-TZD	ALD/AMN, other	MPC Inhibitor						

Imeglimin: orally-available drug candidate for the treatment of type 2 diabetes. It has a unique mechanism of action targeting mitochondrial dysfunction, enabling it to simultaneously target the two key defects that cause diabetes – impaired pancreatic b-cell function and insulin resistance. It has an extensive and consistent data package with 25 clinical studies in over 2,500 subjects and has been shown to have robust efficacy both alone and in combination with other drugs currently on the market. Imeglimin has also been shown to be well tolerated and to have a safety profile similar to placebo.

PXL770: orally available first-in-class product targeting adenosine monophosphate-activated protein kinase (AMPK). Through its unique mechanism of action that directly activates AMPK, PXL770 modulates multiple metabolic and immune-related pathways. This target, which plays a key role as a master regulator of cellular energy, has the potential to treat several chronic metabolic diseases, including diseases that affect the liver, such as NASH.

PXL065: (deuterium-stabilized R-pioglitazone), modulates non-genomic metabolic pathways, it is advancing into a Phase 2 clinical trial. Based upon preclinical and Phase 1a results, PXL065 is expected to exhibit a better therapeutic profile than pioglitazone for NASH, including efficacy with reduced side effects, such as those associated with the activation of PPAR- γ (weight gain, fractures and edema).

Due to COVID-19, Poxel is monitoring all developments that might impact the timelines for achievement of our corporate objectives and we will continue to update you as needed.

A STRATEGIC PARTNERSHIP FOR IMEGLIMIN



Sumitomo Dainippon
Pharma

Poxel and Sumitomo Dainippon Pharma have a strategic partnership for the development and commercialization of Imeglimin in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries¹. On July 30, 2020, Poxel announced that Sumitomo Dainippon Pharma submitted a J-NDA to the Pharmaceuticals and Medical Devices Agency (PMDA) to request approval for manufacturing and marketing of Imeglimin for the treatment of type 2 diabetes.

- **Phase 3 TIMES program successfully completed in Japan observed to show robust efficacy with favorable safety and tolerability profile**
 - Positive results from TIMES 1, TIMES 2 and TIMES 3
 - A New Drug Application in Japan (J-NDA) is currently advancing through regulatory review
 - Product launch targeted in 2021 in Japan²
- **Potential of up to \$253M³ in development and regulatory milestones, and sales-based payments**
- **Escalating double-digit royalties on net sales**
- **The J-NDA approval would trigger a milestone payment of EUR 14.2 million (\$16.6 million)⁴**
- **Sumitomo #1 diabetes franchise; Guidance FY20 \$900M²**

1. including: Indonesia, Vietnam, Thailand, Malaysia, the Philippines, Singapore, Myanmar, Cambodia, and Laos.

2. Year noted is Fiscal Year from April 2021 to March 2022, which is Sumitomo Dainippon Pharma's Fiscal Year

3. Converted at the exchange rate at the date of the agreement

4. Converted at the exchange rates as of June 30, 2020.

NEAR-TERM MILESTONES EXPECTED TO DRIVE VALUE

IMEGLIMIN

2021

- J-NDA approval; triggers ~€14.2M and ability to draw down €13.5M from IPF loan*
- Poxel regained Imeglimin rights from Metavant for the US, Europe and other countries not covered by our agreement with Sumitomo Dainippon Pharma and is considering various options to advance Imeglimin in those countries

PXL770

H2 2021

- Initiation of **Ph 2b** trial with biopsy-proven NASH patients

PXL065

2021

- Complete **Ph 2** recruitment mid-2021

2022

- Results for single **Ph 2** trial mid-2022

PREVALENCE

Prevalence of type 2 diabetes

In 2017, 425 million people aged 20 to 79 years old worldwide were suffering from diabetes, with over 90% from type 2 diabetes (International Diabetes Federation)

Prevalence of NASH

Today, approximately 40 million people are affected by NASH in the U.S., France, Germany, Italy, Spain, the United Kingdom and Japan (Decision Resources); Prevalence of type 2 diabetes in patients with NASH estimated to be 47%; approximately 26% of T2DM patients have NASH



*Converted at the exchange rates as of June 30, 2020.

SHAREHOLDER TOOLS

If you wish to receive upcoming press releases from POXEL via email, simply send your **surname, name** and **email address** to poxel@trophic.eu

POXEL ON THE STOCK EXCHANGE

Market	Euronext Paris since February 2015
Ticker	POXEL
ISIN	FR0012432516
Market cap.	€190 million*
Number of shares	28,611,254
Share price	€6,65*
52-week trading range	€5.49 - €9.63

*as of March 29, 2021. **At the date of the presentation, based on the Company's knowledge.

SHAREHOLDER STRUCTURE**

