



Minoryx and Neuraxpharm announce a strategic alliance to provide a new therapy for rare CNS disease patients in Europe

The companies enter into a license agreement for the European rights to leriglitazone, currently under EMA review for the orphan indication X-linked Adrenoleukodystrophy (X-ALD)

Mataró, Barcelona (Spain) and Düsseldorf (Germany), November 10, 2022 - [Minoryx Therapeutics](#), a late-stage biotech company focused on the development of treatments for orphan central nervous system (CNS) disorders and the [Neuraxpharm Group](#) ("Neuraxpharm"), a leading European specialty pharmaceutical company focused on CNS therapies, today announce the completion of a strategic license agreement.

Under the agreement, Minoryx grants Neuraxpharm exclusive European rights to its lead candidate [leriglitazone](#), a novel, brain penetrant and selective PPAR gamma agonist. Neuraxpharm obtains exclusive rights to commercialize leriglitazone in Europe and will join with Minoryx to continue the further development of leriglitazone. Minoryx retains full rights to leriglitazone in the US and the rest of world, excluding already partnered China.

As part of the agreement, Neuraxpharm has agreed to pay Minoryx a significant double-digit upfront payment in addition to milestone payments and development funding totalling up to EUR 258 million in the aggregate. Also, Minoryx will further receive material tiered double-digit royalties.

Minoryx and Neuraxpharm will collaborate on concluding the ongoing European regulatory process to obtain approval for leriglitazone for the treatment of adult male patients with [X-ALD](#). Leriglitazone will be the first approved treatment for this population if it is approved by the European Medicines Agency (EMA). Minoryx and Neuraxpharm are further committed to jointly continue the development of leriglitazone for additional X-ALD patient populations and other orphan indications.

Tapping into the business segment of orphan drugs to treat rare diseases via this license agreement is a new approach for Neuraxpharm. In this strategically relevant step, the company builds on its extensive CNS expertise stemming from 35 years in the field of CNS disorders. Neuraxpharm will create a centre of excellence dedicated to leriglitazone. With this, Neuraxpharm plans to accelerate diagnosis and allow for early treatments through better population screening and shorter referral ways.

Another important part of the work will consist of closely collaborating with patient advocacy groups and associations.

“This agreement is not only an important strategic step for Neuraxpharm, it will also be to the benefit of patients who may not be too numerous but whose medical needs are as urgent as they can get. Helping them and at the same time entering a highly attractive business area with a great partner like Minoryx is something I am very proud of,” said Dr. Jörg-Thomas Dierks, CEO of Neuraxpharm.

“Minoryx remains fully committed to ensure that leriglitzone reaches X-ALD patients as quickly as possible. With the Neuraxpharm partnership Minoryx has secured a strong partner that will enable an optimal launch of leriglitzone throughout Europe. Minoryx selected Neuraxpharm specifically for its expertise in the European central nervous system marketplace and its substantial experience and capabilities in successfully commercializing CNS drugs in Europe,” said Marc Martinell, CEO, Minoryx. *“Minoryx will continue the development and regulatory preparations for the US and is currently in discussions with the FDA to define the next steps for the US approval path.”*

About leriglitzone

Leriglitzone (MIN-102) is a novel, brain penetrant and selective PPAR gamma agonist under development for treatment of X-linked adrenoleukodystrophy (X-ALD) and other orphan CNS diseases. Leriglitzone has been granted orphan drug status from the EMA and the FDA as well as fast track and rare pediatric disease designation from the FDA for the treatment of X-ALD. On September 14, 2022, Minoryx announced that the EMA had validated the filing of its Marketing Authorization Application (MAA) for the treatment of adult male patients with [X-ALD](#).

About X-ALD

X-ALD (X-linked adrenoleukodystrophy) is an orphan neurodegenerative disease. The global incidence of X-ALD is approximately 6-8/100,000 live births. As a disease linked to the X chromosome it presents mostly in male. However, its chronic form also affects women even though they develop symptoms later in life. X-ALD patients reaching adulthood develop adrenomyeloneuropathy (AMN), characterized by progressive spastic paraparesis, as well as progressive deterioration of balance and sensory function, and development of incontinence. This form progresses chronically with onset of symptoms in adulthood and has a poor prognosis.

Recent literature indicates that up to 60% of adult male X-ALD patients will also develop cALD (cerebral ALD), which typically affects boys with an age of onset between 4-8 years. cALD is characterized by aggressive brain inflammation, and if untreated, patients progress quickly with severe neurological impairment, often leading to permanent disability and death within 2-4 years.

There is currently no pharmacological treatment available for adults with X-ALD. In childhood, hematopoietic stem cell transplantation (HSCT) or ex-vivo gene therapy can arrest the disease, however, it is an aggressive procedure and only available for a portion of patients. In adults, experience in HSCT is very limited and the intervention is often not recommended.

Advisors

MTS Health Partners, L.P. is acting as financial advisor to Minoryx. Baker McKenzie LLP is acting as legal advisor to Minoryx in connection with the transaction. Neuraxpharm was advised by Clifford Chance in the legal matters related to this transaction.

About the Neuraxpharm Group

The European CNS specialist Neuraxpharm is a leading specialty pharmaceutical company focused on the treatment of central nervous system disorders (CNS) with a direct presence in 19 countries in Europe. Backed by funds advised by Permira, Neuraxpharm has a unique understanding of the CNS market built over 35 years.

With its focus on CNS, Neuraxpharm develops and commercializes established brands, value added medicines, generics, Consumer Healthcare products, medical cannabis, beyond-the-pill solutions (digital health and medical devices) and orphan drugs and is continuously striving to offer a wide range of effective, high quality and affordable CNS treatment options in Europe.

Present with its products in more than 50 countries, Neuraxpharm also manufactures pharmaceutical products and active pharmaceutical ingredients in its own manufacturing sites, Lesvi and Inke, in Spain.

For more information, please visit <https://www.neuraxpharm.com>

About Minoryx

Minoryx is a registration stage biotech company focusing on the development of novel therapies for orphan CNS diseases with high unmet medical needs. The company's lead program, leriglitazone (MIN-102), a novel, brain penetrant and selective PPAR gamma agonist, is being developed in X-linked Adrenoleukodystrophy (X-ALD) and other orphan CNS diseases. The company is backed by a syndicate of experienced investors, which includes Columbus Venture Partners, CDTI Innvierte, Caixa Capital Risc, Fund+, Ysios Capital, Roche Venture Fund, Kurma Partners, Chiesi Ventures, S.R.I.W, Idinvest Partners / Eurazeo, SFPI-FPIM, HealthEquity, Sambrinvest and Herrecha, and has support from a network of other organizations. Minoryx was founded in 2011, is headquartered in Spain with Belgian facilities and has so far raised more than €115 million.

For more information, please visit www.minoryx.com

Minoryx Contact Information:

Image Box Communications

Neil Hunter / Michelle Boxall

Tel +44 (0)20 8943 4685

neil@ibcomms.agency / michelle@ibcomms.agency

Neuraxpharm Contact Information:

FGS Global

Caroline Schröder

Phone: +49 151 16308949

caroline.schroeder@fgsglobal.com