Viatris Completes Acquisition of Aculys Pharma Including Exclusive Rights to Pitolisant in Japan and to Spydia® in Japan and Certain Other Markets in the Asia-Pacific Region

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- *Strengthens Viatris' Presence in Japan With the Addition of Two Innovative Assets Targeting Areas of Significant Unmet Medical Need*
- *Leverages Existing Infrastructure and Expertise in Central Nervous System Therapy Area*
- *Aligned with Strategy to Target Accretive Regional Business Development Opportunities*

PITTSBURGH, Oct. 15, 2025 /PRNewswire/ -- **Viatris Inc**. (Nasdaq: VTRS), a global healthcare company, today announced it has acquired Aculys Pharma, Inc., a clinical stage biopharmaceutical company focused on commercializing innovative treatments for neurological conditions. Viatris received rights to develop and commercialize pitolisant and Spydia®, two assets in the Central Nervous System (CNS) therapy area, further expanding Viatris' portfolio of innovative products in Japan.

As part of the transaction, Viatris has acquired exclusive development and commercialization rights in Japan for pitolisant, a selective/inverse agonist of the histamine H3 receptor. Based on the strength of recent Phase 3 clinical trial results in Japanese patients and the positive benefit-risk profile established globally, Viatris is on track to file for marketing approval from the Ministry of Health, Labour and Welfare (MHLW) of Japan for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy and for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea syndrome (OSAS) by the end of 2025.

The transaction also includes exclusive rights in Japan and certain other markets in the Asia-Pacific region for Spydia Nasal Spray, which was approved in Japan in June 2025 for the treatment of status epilepticus.

"The acquisition of Aculys Pharma leverages our deep commercial infrastructure in Japan and longstanding expertise in CNS, positioning us to bring these innovative treatments to more patients in need," said **Corinne Le Goff,** Chief Commercial Officer, Viatris. "The addition of pitolisant and Spydia to our portfolio of innovative products is strategically aligned with our commitment to grow in areas where we can make the greatest impact and is a great example of our business development strategy designed to complement our core strengths in markets across the world."

This acquisition further expands Viatris' portfolio of innovative products in Japan which includes Effexor for the treatment of generalized anxiety disorder (GAD) which is under regulatory review, selatogrel in Acute MI, Nefecon in IgA nephropathy, and cenerimod in systemic lupus erythematosus (SLE), all of which have pivotal Phase 3 trials currently on going and Tyrvaya in dry eye disease for which a Phase 3 trial is anticipated to start in 2026.

Terms of the Transaction
Under the terms of the acquisition agreement, Viatris has made an upfront payment to Aculys Pharma shareholders as consideration for the acquisition, with additional consideration contingent upon the achievement of specified regulatory and commercial milestones, and royalties on net sales.

About Pitolisant
Pitolisant is an antagonist/inverse agonist that selectively binds to the histamine H3 receptor, an autoreceptor located in the presynaptic region of the histamine-containing neurons in the human brain that plays a critical role in regulating sleep and wake rhythm. The drug was approved by the European Medicines Agency (EMA) for the treatment of narcolepsy with or without cataplexy in 2016 and for the treatment of excessive daytime sleepiness associated with OSAS in 2021. In 2019, the U.S. Food and Drug Administration (FDA) approved pitolisant under the brand name Wakix® for the treatment of excessive daytime sleepiness associated with narcolepsy and cataplexy associated with narcolepsy in 2020. As of the end of 2023, pitolisant had obtained regulatory approval in 38 countries including the U.S. and the EU for the treatment of narcolepsy, and in 29 countries in the EU for the treatment of OSAS.

Positive Pivotal study results in Japanese patients were recently achieved in both narcolepsy and OSAS. In the narcolepsy Phase 3 trial, the primary endpoint of improvement in excessive daytime sleepiness (EDS) compared to a placebo group using the Epworth Sleepiness Scale (ESS) was met. Statistically significant difference in ESS was observed between the two groups. Furthermore, the key secondary endpoint of the frequency of cataplexy attacks showed a suppression effect comparable to that observed in prior global Phase 3 trials. No serious adverse events were noted, and the safety and tolerability results were consistent with global clinical trials.

The OSAS Phase 3 trial evaluated the effect of pitolisant in Japanese patients with OSAS who were experiencing residual EDS despite treatment with CPAP therapy. At the end of the 12-week treatment period, patients receiving pitolisant scored lower on the ESS used to measure EDS compared to those in the placebo group and this difference was statistically significant (p=0.007). Additionally, safety and tolerability were consistent with results from global clinical studies.

About Spydia (diazepam)
In Japan, Aculys Pharma received marketing approval for Spydia Nasal Spray 5 mg, 7.5 mg, and 10 mg for the treatment of status epilepticus in patients 2 years or older in June 2025. This is the first intranasal anti-seizure medication approved in Japan for the treatment of status epilepticus or

seizures with potential progression to status epilepticus. It is also the first rescue medication approved for adults for out-of-hospital use.

This drug was developed by Neurelis, Inc. in the US and Aculys Pharma obtained exclusive development and commercialization rights in Japan and certain markets in the Asia-Pacific region, including Australia, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, New Zealand, Philippines, South Korea, Thailand and Vietnam. In 2020, the FDA approved diazepam nasal spray under the brand name Valtoco® for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a usual seizure pattern in patients with epilepsy aged 6 years and older. In April 2025, the FDA extended the indication to include patients aged 2 years and older. Diazepam has been used for approximately 60 years in Japan, primarily in injectable form as a treatment for epileptic seizures.

About Viatris

Viatris Inc. (Nasdaq: VTRS) is a global healthcare company uniquely positioned to bridge the traditional divide between generics and brands, combining the best of both to more holistically address healthcare needs globally. With a mission to empower people worldwide to live healthier at every stage of life, we provide access at scale, currently supplying high-quality medicines to approximately 1 billion patients around the world annually and touching all of life's moments, from birth to the end of life, acute conditions to chronic diseases. With our exceptionally extensive and diverse portfolio of medicines, a one-of-a-kind global supply chain designed to reach more people when and where they need them, and the scientific expertise to address some of the world's most enduring health challenges, access takes on deep meaning at Viatris. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at viatris.com and investor.viatris.com, and connect with us on LinkedIn, Instagram, YouTube and X.

About Aculys Pharma, Inc.

Aculys Pharma is a clinical stage biopharmaceutical company that is pioneering ways to eliminate drug lag/drug loss in Japan and is working to resolve social issues related to neurological and psychiatry diseases. Its corporate name was created from the philosophy of serving as a "Catalyst to Access". Aiming to act as a bridge for innovative medical care in the field of neuropsychiatry, Aculys Pharma develops and commercializes novel pharmaceuticals introduced from the US and European countries and provides innovations for better medical care to patients, their families, healthcare professionals, and society.

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include statements regarding Viatris completes acquisition of Aculys Pharma including exclusive rights to pitolisant in Japan and to Spydia® in Japan and certain other markets in the Asia-Pacific region; strengthens Viatris' presence in Japan with the addition of two innovative assets targeting areas of significant unmet medical need; leverages existing infrastructure and expertise in Central Nervous System therapy area; aligned with strategy to target accretive regional business development opportunities; based on the strength of recent Phase 3 clinical trial results in Japanese patients and the positive benefit-risk profile established globally, Viatris is on track to file for marketing approval from the Ministry of Health, Labour and Welfare (MHLW) of Japan for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy and for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea syndrome (OSAS) by the end of 2025; the acquisition of Aculys Pharma leverages our deep commercial infrastructure in Japan and longstanding expertise in CNS, positioning us to bring these innovative treatments to more patients in need; the addition of pitolisant and Spydia to our portfolio of innovative products is strategically aligned with our commitment to grow in areas where we can make the greatest impact and is a great example of our business development strategy designed to complement our core strengths in markets across the world; this acquisition further expands Viatris' portfolio of innovative products in Japan which includes Effexor for the treatment of generalized anxiety disorder (GAD) which is under regulatory review, selatogrel in Acute MI, Nefecon in IgA nephropathy, and cenerimod in systemic lupus erythematosus (SLE), all of which have pivotal Phase 3 trials currently on going and Tyrvaya in dry eye disease for which a Phase 3 trial is anticipated to start in 2026; under the terms of the acquisition agreement, Viatris has made an upfront payment to Aculys Pharma shareholders as consideration for the acquisition, with additional consideration contingent upon the achievement of specified regulatory and commercial milestones, and royalties on net sales; positive Pivotal study results in Japanese patients were recently achieved in both narcolepsy and OSAS; in the narcolepsy Phase 3 trial, the primary endpoint of improvement in excessive daytime sleepiness (EDS) compared to a placebo group using the Epworth Sleepiness Scale (ESS) was met; statistically significant difference in ESS was observed between the two groups; furthermore, the key secondary endpoint of the frequency of cataplexy attacks showed a suppression effect comparable to that observed in prior global Phase 3 trials; no serious adverse events were noted, and the safety and tolerability results were consistent with global clinical trials; the OSAS Phase 3 trial evaluated the effect of pitolisant in Japanese patients with OSAS who were experiencing residual EDS despite treatment with CPAP therapy; at the end of the 12-week treatment period, patients receiving pitolisant scored lower on the ESS used to measure EDS compared to those in the placebo group and this difference was statistically significant (p=0.007); additionally, safety and tolerability were consistent with results from global clinical studies. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: Viatris not realizing the anticipated benefits of the acquisition; the uncertainties inherent in research and development, including the outcomes of clinical trials; the ability to meet anticipated clinical endpoints; the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from clinical studies; actions and decisions of healthcare and pharmaceutical regulators; our ability to comply with applicable laws and regulations; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any regulatory, legal or other impediments to Viatris' ability to bring new products to market; products in development and/or that receive regulatory approval may not achieve expected levels of market acceptance, efficacy or safety; longer review, response and approval times as a result of evolving regulatory priorities and reductions in personnel at health agencies; Viatris' or its partners' ability to develop, manufacture, and commercialize products; the scope, timing and outcome of any ongoing legal proceedings, and the impact of any such proceedings on Viatris; Viatris' failure to achieve expected or targeted future financial and operating performance and results; goodwill or impairment charges or other losses; any changes in or difficulties with Viatris' manufacturing facilities; risks associated with international operations; changes in third-party relationships; the effect of any changes in Viatris' or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatris or its partners; uncertainties regarding future demand, pricing and reimbursement for Viatris' products; uncertainties and matters beyond the control of management, including but not limited to general political and economic conditions, potential adverse impacts from future tariffs and trade restrictions, inflation rates and global exchange rates; and the other risks described in Viatris' filings with the Securities and Exchange Commission ("SEC"). Viatris routinely uses its website as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Viatris undertakes no obligation to update these statements for revisions or changes after the date of this press release other than as required by law.

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