Angelini Pharma Presents Long-Term Data for cenobamate Demonstrating Benefit in Adults Living with Epilepsy

ROME, ITALY, September 19, 2024 /EINPresswire.com/ -- - Findings from a post-hoc analysis of the C017 open-label extension (OLE) study demonstrated long-term reduction in seizure frequency with cenobamate, approved as adjunctive treatment in patients with focal onset seizures, after five years across eight different etiology categories
- Post-hoc analysis of the C021 study showed high retention rates at year three regardless of etiology categories, ranging from 60.3% to 77.9%
- Additional data of C021 highlighted better tolerability of cenobamate as add-on to only one anti-seizure medication (ASM), as measured by fewer and less severe adverse events and faster time to resolution

Angelini Pharma, part of the privately owned Angelini Industries, shared positive findings from its clinical trials in epilepsy, demonstrating that adjunctive treatment with cenobamate provided seizure reduction and high retention rates across a variety of epilepsy etiologies as well as a favorable long-term tolerability profile in patients with uncontrolled focal-onset epilepsy. These results were presented as part of the 15th European Epilepsy Congress (EEC).

Cenobamate is an anti-seizure medication (ASM) approved in Europe1 as adjunctive treatment of focal-onset seizures with or without secondary generalization in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products. In the United Kingdom (UK), cenobamate has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) as an adjunctive treatment for focal-onset seizures with or without secondary generalization in adult patients with epilepsy who have not been adequately controlled despite treatment with at least two anti-epileptic medicinal products.2

Epilepsy is a heterogeneous disorder with diverse causes and etiologies. Some of these etiologies like Mesial Temporal Sclerosis (MTS) are more difficult to treat and associated with a higher risk of drug resistance and therefore poorer outcomes.3 In a post-hoc analysis of the C017 open-label extension (OLE) study (abstract #232), adjunctive cenobamate showed high efficacy over five years across all etiologies studied, including high rates of responders living with structural epilepsies like MTS (64.7%). These long-term findings across eight different etiology categories suggest the potential therapeutic role of cenobamate in the long-term treatment of a broad range of etiologies, including those considered among the most difficult to treat.

“Patients with a high risk of drug-resistant epilepsy may profit from earlier interventions with innovative treatments,” said Dr. José María Serratosa Fernández, Hospital Universitario Fundación Jiménez Díaz, Madrid (Spain). “Anti-seizure medications are helping patients achieve seizure freedom across the diverse spectrum of etiologies.”

An additional post-hoc analysis assessed retention rates in the cenobamate C021 study across eight definite or possible epilepsy etiologies (abstract #238). In line with findings from the C017 OLE, these data showed treatment with cenobamate over a three-year period was associated with high retention rates independent of the etiology. Retention rates ranged from 76.3% to 91.7% at year one, from 64.4% to 86.7% at year two and from 60.3% to 77.9% at year three. Retention rates provide a proxy measure of long-term tolerability, safety and efficacy, showing that cenobamate might be an effective treatment regardless of etiology.

A further post-hoc analysis evaluated the adverse event (AE) severity, duration and time to resolution of the most common adverse events in the cenobamate C021 study (abstract #239). Data from this analysis showed patients treated with cenobamate added on to a single ASM reported a better tolerability profile than those receiving cenobamate as an add on to two or more additional ASMs. Tolerability in this analysis was measured by fewer and less severe treatment-emergent AEs (TEAEs) and faster time to resolution when TEAEs occurred. These data suggest earlier use of cenobamate alongside the potential reduction of concomitant ASMs may lead to better tolerability.

These findings for cenobamate are investigational only. Please refer to the Summary of Product Characteristics1,2 for approved treatment indications with cenobamate.

“Continued studies on anti-seizure medications are vital to understanding the long-term impact on seizure control and treatment retention,” said Rafal Kaminski, Chief Scientific Officer, Angelini Pharma. “With an estimated 50 million individuals affected by epilepsy globally, our aim is to enhance the management of seizures, increase the accessibility and tolerability of treatments, ultimately achieving seizure-freedom for people living with epilepsy.”

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card System at www.MHRA.gov.uk/yellowcard for the UK or www.hpra.ie for Ireland.

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About Epilepsy
Epilepsy is one of the most widespread neurological diseases in the world, affecting globally approximately 50 million people of all ages.4 In Europe, up to six million people are estimated to

be living with this disease.5 Epilepsy can have multiple potential causes, including structural, metabolic, genetic and other factors, though approximately half of cases worldwide do not have a known cause.4

The complications associated with epilepsy are severe, with a risk of premature mortality up to three times higher than the general population.4 The recurrent seizures associated with this condition also have wide-ranging effects on a person's broader physical and mental health, education and employment opportunities and other quality of life factors.4

Treatments are available to help reduce seizures and improve quality of life, however approximately 40% of people living with epilepsy are still uncontrolled despite the treatment with two ASMs.6

About the C017 Open-Label Extension Study
C017 was a multicenter, double-blind, randomized, placebo-controlled, dose-response study to evaluate the safety and efficacy of cenobamate as an adjunctive therapy in adults with uncontrolled focal epilepsy despite treatment with one to three anti-seizure medications (ASMs). Patients who completed the double-blind study and met study eligibility criteria had the option to enroll in an open-label extension (OLE) to provide additional insight into the long-term clinical and safety profile of adjunctive cenobamate.

About the C021 Open-Label Extension Study
C021 was a multicenter, open-label Phase 3 study assessing the safety of cenobamate as adjunctive therapy in 1,339 adults (18-70 years old) with uncontrolled focal seizures despite treatment with one to three antiseizure medications (ASMs). The objectives of the study included the characterization of the long-term safety of cenobamate and to understand how to best add cenobamate to regimens that included phenytoin or phenobarbital. In addition, the study was designed to determine the rate of DRESS in at least 1,000 patients taking cenobamate for at least six months, using a low starting dose and every other week titration. Cenobamate was initiated at 12.5 mg/day and increased at 2-week intervals to 25, 50, 100, 150 and 200 mg/day. Further increases to 400 mg/day using bi-weekly 50 mg/day increments were allowed.

About ONTOZRY® (cenobamate□)
The product is an anti-seizure medication (ASM) approved in Europe as adjunctive treatment of focal-onset seizures with or without secondary generalization in adult patients living with epilepsy who have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products.1 In the United Kingdom (UK), cenobamate has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) as an adjunctive treatment for focal-onset seizures with or without secondary generalization in adult patients with epilepsy who have not been adequately controlled despite treatment with at least two anti-epileptic medicinal products.2

The product is a novel small molecule that provides a dual, complementary mechanism of action

aimed at reducing seizures. The dual mechanism of action suggests that it has the potential to both prevent seizure initiation and limit seizure spread.7,8 The precise mechanism of action by which cenobamate exercises its therapeutic effects in patients with focal-onset seizures is unknown.

Cenobamate was discovered and developed by SK Biopharmaceuticals and its U.S. subsidiary SK Life Science.

Long-term data on the product was studied in open-label extensions of the double-blind placebo-controlled trials, as well as the open-label safety studies in adults with uncontrolled focal-onset seizures. Additionally, cenobamate was assessed in a randomized, double-blind, placebo-controlled trial evaluating its safety and efficacy as adjunctive therapy in patients with primary generalized tonic-clonic seizures (NCT03678753).9–13

About Angelini Pharma
Angelini Pharma is an international pharmaceutical company, part of the privately owned multi-business Angelini Industries. The Company researches, develops and commercializes health solutions with a focus on the areas of Brain Health, including Mental Health and Epilepsy, and Consumer Health. Founded in Italy at the beginning of the 20th century, Angelini Pharma operates directly in 20 countries, employing more than 3,000 people. Its products are marketed in over 70 countries through strategic alliances with leading international pharmaceutical groups. For more information about Angelini Pharma please visit https://www.angelinipharma.com.

About Angelini Industries
Angelini Industries is a multinational industrial group founded in Ancona in 1919 by Francesco Angelini. Today, Angelini Industries represents a solid and diversified industrial reality that employs approximately 5,800 employees and operates in 21 countries around the world with revenues of over 2 billion euros, generated in the health, industrial technology, and consumer goods sectors. A targeted investment strategy for growth; constant commitment to research and development; deep knowledge of markets and business sectors, make Angelini Industries one of the Italian companies of excellence in the sectors in which it operates. To learn more visit www.angeliniindustries.com.

References
1. Ontozry Summary of Product Characteristics. European Medicines Agency, https://www.ema.europa.eu/en/documents/product-information/ontozry-epar-product-information_en.pdf. Accessed July 2024.
2. MHRA Public Assessment Report, National Procedure - Ontozry. https://mhraproducts4853.blob.core.windows.net/docs/4ca617340a45337e5d0c3e22ceb4a133b90950fc. Accessed July 2024.
3. Roy et al. Seizure (2019) 46-50.
4. WHO. “Epilepsy Key Facts.” N.p., 9 Feb. 2023. Web. 24 Aug. 2023.

5. Behr et al. Epidemiology of epilepsy. Revue Neurologique 2016 Jan; 172(1):27-36. doi: .1016/j.neurol.2015.11.003
6. Chen Z, Brodie MJ, Liew D, Kwan P. Treatment Outcomes in Patients With Newly Diagnosed Epilepsy Treated With Established and New Antiepileptic Drugs: A 30-Year Longitudinal Cohort Study. JAMA Neurol. 2018 Mar 1;75(3):279-286. doi: 10.1001/jamaneurol.2017.3949. Erratum in: JAMA Neurol. 2018 Mar 1;75(3):384. doi: 10.1001/jamaneurol.2018.0018. PMID: 29279892; PMCID: PMC5885858.
7. Guignet et al. Epilepsia 2020;61:2329–39
8. Löscher et al. Epilepsia 2021;62:596–614
9. French et al. Epilepsia 2021;62:2142–50
10. Klein et al. Neurology 2022, 99 (10) e989–e998
11. Chung et al. Neurology 2020;94:e2311–e22
12. Krauss et al. Lancet Neurol 2020;19:38–48
13. Sperling et al. Epilepsia 2020;61:1099–108

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