

ReST Therapeutics receives endorsement from the EMA to enter clinical phase & request First in Human trials for FENM®

ReST Therapeutics is developing breakthrough therapies to treat Alzheimer Disease (AD) and PTSD with its flagship product FENM®.

MONTPELLIER, FRANCE, February 24, 2023 /EINPresswire.com/ -- [ReST Therapeutics](#), clinical-stage biotech company developing breakthrough therapies to treat Alzheimer Disease (AD) and Post-Traumatic Stress Disorder (PTSD), today announced that it has received the endorsement of the European Medical Authority (EMA) to enter First in Human clinical trials for its flagship product FENM®.

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We are on track to start FIH in 2023, covered by our \$5m seed financing. To ramp up our development, we plan to launch our Series A funding of \$20m to take us up to Phase IIa clinical trials”

Dr Gilles Rubinstenn, CEO

“We are delighted to have received this encouraging scientific advice from the EMA and can now move to the next important stage in developing FENM®. This endorsement ensures that we are completely on track with

our plans to start FIH this year, which was covered by our successful \$5m seed financing. As we now look to ramp up our development, we plan to launch our Series A funding round of \$20m to take us through to Phase IIa clinical trials.”

declared Dr Gilles

Rubinstenn, CEO & Co-Founder of ReST Therapeutics.

“We will request the authorization for a First in Human Trial from a European National Competent Health Authority in the coming weeks, and we are very excited to be able to test the safety and tolerance of our drug treatment candidate in our first patients. We are confident that we can prove that FENM® has the potential to be a treatment solution for patients suffering from PTSD, where today no adequate solution exists.” commented Dr Florent Perin-Dureau, CMO & Co-Founder of ReST Therapeutics.

AD is a major medical issue in the context of an aging population and the lack of effective treatment. PTSD affects nearly 16m people in the US and Europe and costs society hundreds of billion dollars/year. (80% of [PTSD sufferers](#) have experienced severe trauma in civilian society such as physical or sexual assault, abuse and serious accidents)

(Source: <https://pubmed.ncbi.nlm.nih.gov/35485933/>)

ReST Therapeutics' mission is to develop the molecule FENM®, initially developed as a biomarker of the brain receptor NMDA*, as a treatment solution. Preclinical trials have had very promising results and were conducted simultaneously in France (with the University of Montpellier and the ENS-Paris Ecole Normale Supérieure - Paris Sciences Lettres) and in the United States (with Columbia University). FENM® also has protective properties against cellular and cognitive damage associated with neurodegenerative diseases such as Alzheimer's disease.

ReST Therapeutics received a formal scientific advice from the European Medicine Agency for the development of its flagship product FENM® at the end of January 2023. This followed the final report being approved by the Scientific Advice Working Party (SAWP) and adopted by the Committee for Medicinal Products for Human Use (CHMP). The approach chosen by ReST Therapeutics, aimed at ensuring the safety of the patients involved, while accessing the tolerance pharmacokinetics of FENM, was endorsed by EMA and no objection was issued.

ReST Therapeutics will request the authorization of its First in Human Trial from a European National Competent Health Authority through the new CTIS portal system, in the coming weeks.

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