



Greenwich Biosciences to Present Analysis of Three Clinical Studies of Nabiximols for People with Multiple Sclerosis Related Spasticity at the American Academy of Physical Medicine and Rehabilitation (AAPM&R) Annual Assembly

November 13, 2020

- Results from analysis of three Phase 3 clinical studies showed statistically significant improvement in spasticity in people with multiple sclerosis

- Treatment with nabiximols seen in this analysis was not associated with increased muscle weakness or a notable change in preferred walking speed

CARLSBAD, Calif., Nov. 13, 2020 (GLOBE NEWSWIRE) -- Greenwich Biosciences, U.S. subsidiary of GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), a world leader in the science, development, and commercialization of cannabinoid prescription medicines, will present data from an analysis of three Phase 3 clinical trials of nabiximols in spasticity among persons with multiple sclerosis (MS) at the American Academy of Physical Medicine and Rehabilitation (AAPM&R) Virtual Annual Assembly. The research will be presented live during the November 14 Research Spotlight session on Neurological Rehabilitation. The analysis showed that the statistically significant improvement in spasticity observed with nabiximols in all three trials was not accompanied by an increase in muscle weakness or decrease in preferred walking speed.

"Between 60 and 90 percent of people with multiple sclerosis report experiencing spasticity; and muscle weakness can be a serious side effect with current anti-spasticity medications," said Francois Bethoux, MD, Director of Rehabilitation Services, The Mellen Center for Multiple Sclerosis Treatment and Research, The Cleveland Clinic Foundation, and a consultant to GW Pharmaceuticals. "Muscle weakness in MS is more than feeling weak; it represents genuine difficulty in moving and can make even daily activities like walking and dressing challenging. We are encouraged that the data from these trials showed that nabiximols not only improved patient-reported spasticity but also did not appear to increase muscle weakness or negatively affect preferred walking speed."

Data from three randomized, placebo-controlled trials of nabiximols (GWMS0106, GWSP0604, and SAVANT) conducted in Europe were analyzed to assess the relationship between measures of spasticity and muscle strength in lower extremities or walking speed. Spasticity was evaluated using the Numerical Rating Scale (NRS) in all three trials, muscle strength using Motricity Index (MI) in GWMS0106 and GWSP0604, and mobility using timed 10-Meter Walk Test (10MWT) in GWSP0604 and SAVANT. All three trials enrolled persons with MS-related spasticity inadequately managed by current medications.

- GWMS0106: Nabiximols significantly improved mean NRS spasticity score vs. placebo (-0.52 points; p=0.048), without significantly affecting the MI for legs (3.86, p=0.054).
- GWSP0604: Nabiximols significantly improved mean NRS spasticity score from baseline vs. placebo (-0.84, p=0.0002), without significantly affecting the MI for legs (0.97, p=0.439) or the 10MWT results (-3.34, p=0.069).
- SAVANT: Nabiximols significantly improved mean NRS spasticity vs. placebo (-1.9, p<0.0001), without significantly affecting the 10MWT results (-1.71, p=0.11).

The analysis included data from 184 participants in GWMS0106, 241 participants in GWSP0604, and 106 participants in SAVANT.

Nabiximols is approved by regulatory bodies in 28 countries outside the United States to treat MS spasticity. GW recently initiated the first global Phase 3 clinical trial studying nabiximols for MS spasticity that will engage patients and investigators in the United States. The first trial is one of five new pivotal studies planned for nabiximols in MS spasticity globally, with the remaining studies on track to commence later in 2020 or in 2021.

"These studies, which served as the basis for nabiximols regulatory approvals outside the U.S., provide important insights into the potential of nabiximols for people with MS-related spasticity," said Justin Gover, GW's Chief Executive Officer. "We are now recruiting participants for the first nabiximols Phase 3 clinical trial in the U.S. in pursuit of our goal of bringing to market the first FDA-approved medicine derived from the whole cannabis plant for the treatment of spasticity in MS."

About Nabiximols

Nabiximols is in pivotal Phase 3 development in the United States for the treatment of MS spasticity. The U.S. commercial rights are owned by GW. In addition to MS spasticity, GW expects to develop nabiximols in Spinal Cord Injury spasticity.

Nabiximols is a complex botanical medicine formulated from extracts of the cannabis plant that contains the principal cannabinoids THC and CBD and also contains minor constituents, including other cannabinoid and non-cannabinoid plant components, such as terpenes, sterols, and triglycerides. The product is administered as an oral spray.

Nabiximols is known as Sativex® outside of the U.S. and is indicated in numerous countries as a treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.¹ These approvals were based on multiple pivotal trials conducted in Europe.² Nabiximols is currently not approved for any indication in the U.S.

About GW Pharmaceuticals plc and Greenwich Biosciences, Inc.

Founded in 1998, GW is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. The Company's lead product, EPIDIOLEX® (cannabidiol) oral solution, is commercialized in the U.S. by its U.S. subsidiary Greenwich Biosciences for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome, or tuberous sclerosis complex (TSC) in patients one year of age and older. This product has received approval in the European Union under the tradename EPIDYOLEX® for the adjunctive treatment of seizures associated with LGS or Dravet syndrome in conjunction with clobazam in patients two years and older and is under EMA review for the treatment of TSC. The Company has a deep pipeline of additional cannabinoid product candidates, in particular nabiximols, for which the Company is advancing multiple late-stage clinical programs in order to seek FDA approval in the treatment of spasticity associated with multiple sclerosis and spinal cord injury. The Company has additional cannabinoid product candidates in clinical trials for autism and schizophrenia. For further information, please visit www.gwpharm.com, and clinicaltrials.gov for updated trial site information and locations.

Forward-looking statement

This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding the timing of clinical trials, the timing of regulatory filings and approvals, the timing and outcomes of regulatory or intellectual property decisions, and the clinical benefits and commercial potential of nabiximols (marketed as Sativex® outside the US). Actual events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the risks and uncertainties which can be found in GW's filings with the U.S. Securities and Exchange Commission. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. GW undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

U.S. Media Enquiries:

Sam Brown Inc. Healthcare Communications

| | |
|----------------|--------------|
| Christy Curran | 615 414 8668 |
| Mike Beyer | 312 961 2502 |

¹ Sativex Oral mucosal Spray, SmPC, <https://www.medicines.org.uk/emc/product/602>

² Markova et al, International Journal of Neuroscience 2019; Novotna et al, European Journal of Neurology 2011; Collin et al, European Journal of Neurology 2007