GW Pharmaceuticals Presents Nabiximols U.S. Development and Commercial Strategy

June 30, 2020

- Potential accelerated pathway to NDA submission -
- Clinical program of five Phase 3 trials provides multiple options for NDA submission, as early as 2021 -
- Webcast featuring a range of guest speakers to be held today from 10:00am-12:00pm EDT -

CARLSBAD, Calif., June 30, 2020 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), a world leader in the science, development, and commercialization of cannabinoid prescription medicines, today announces the Company's strategy for bringing its pipeline product nabiximols to the U.S. market. This strategy includes multiple opportunities for the submission of an initial New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), the earliest of which could occur in 2021. GW will host a webcast today to provide insight into the U.S. Phase 3 clinical program and commercial opportunity for nabiximols.

"We are excited to present the details of our clinical program and regulatory strategy for nabiximols, which we believe support the potential for a substantial near-term commercial opportunity in the U.S. Following constructive meetings with the FDA, we are now commencing a Phase 3 clinical program that provides multiple opportunities for an NDA submission, including as early as 2021", stated Justin Gover, GW's Chief Executive Officer. "Beyond the initial target indication of MS spasticity, our Phase 3 clinical program is designed to achieve a broad spasticity label over time. This development strategy, together with the long-term exclusivity potential of nabiximols, provides GW with confidence that this product should represent a significant value driver for GW."

Highlights of GW's nabiximols U.S. clinical development strategy:
MS Spasticity Clinical program

- Three positive Phase 3 MS spasticity trials already completed outside of the U.S.
- Five new MS Spasticity Phase 3 trials are expected to commence in H2 2020 (2) and H1 2021 (3), any one of which we believe could enable a NDA submission
    - Phase 3 muscle tone studies – placebo-controlled cross-over design
        - N=52; Expected start: Q4 2020
        - N=190; Expected start: Q1 2021
        - N=36 (nabiximols responders); Expected start: Q1 2021
    - Phase 3 spasm frequency studies – placebo-controlled parallel group
        - N=450; Expected start: Q4 2020
        - N=~200 (nabiximols responders); Expected start: Q2 2021

Spinal Cord Injury (SCI) spasticity clinical program

- Three SCI trials are expected to be initiated in 2020 and 2021
    - N=~100 (observational clinical discovery study); Expected start: Q4 2020
    - N=~100 (muscle tone in nabiximols responders); Placebo-controlled parallel group design. Expected start: Q2 2021
    - N=~400 (spasm frequency); Placebo-controlled parallel group design. Expected start: H2 2021

This second spasticity indication may lead to broad anti-spasticity labeling and usage.

Post Traumatic Stress Disorder (PTSD) clinical program

- We are also exploring the potential of nabiximols to reduce sleep disturbance symptoms, as well as anxiety and irritability, in patients with PTSD
- A Phase 2/3 study in PTSD will have approximately 325 subjects and is anticipated to be initiated in H1 2021

GW will host a webcast today, June 30th, 2020 from 10:00am-12:00pm EDT. Justin Gover, GW's Chief Executive Officer, will host this event. The presentation will feature external medical and research experts as well as GW executives. A replay will be available for soon after the live presentation. Both the live webcast link and the archive will be available on GW's corporate website at www.gwpharm.com on the Investor section homepage.

About Nabiximols
Nabiximols is expected to enter pivotal Phase 3 development in the United States in the second half of 2020. The U.S. commercial rights are owned by GW. GW anticipates developing multiple indications for nabiximols with an initial focus on spasticity. The initial target indication will be for the treatment of MS spasticity, to be followed by Spinal Cord Injury spasticity and Post Traumatic Stress Disorder, or PTSD.

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 a mouth spray.

Nabiximols is known as Sativex® outside of the United States and is commercially available for the treatment of MS spasticity in numerous countries. These approvals were based on multiple pivotal trials conducted in Europe[1].

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

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) or Dravet syndrome in patients two years of age or older. This product has received approval in the European Union under the tradename EPIDYOLEX®. The Company has submitted applications in both the U.S. and Europe to expand the indication for Epidiolex to include seizures associated with Tuberous Sclerosis Complex (TSC), for which it has reported positive Phase 3 data, and is carrying out a Phase 3 trial in Rett syndrome. 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, as well as for the treatment of PTSD. The Company has additional cannabinoid product candidates in Phase 2 trials for autism and schizophrenia. For further information, please visit www.gwpharm.com.

Forward-looking statement

This press 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.

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