Eupraxia Pharmaceuticals Inc. Announces Authorization of Clinical Trial Application for Phase 2 Trial of EP-104IAR in Osteoarthritis of the Knee

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VICTORIA, BC, July 19, 2021 /CNW/ - Eupraxia Pharmaceuticals Inc. ("Eupraxia" or the "Company") (TSX: EPRX), a Phase 2 clinical-stage biotechnology company with an innovative drug delivery technology platform, today announced the authorization of its Clinical Trial Application ("CTA") by the Danish Medicines Agency ("DKMA"). The authorization is required to initiate the Company's Phase 2 clinical trial for its lead candidate EP-104IAR as a potential treatment for pain from osteoarthritis ("OA") of the knee.

The trial is being conducted by contract research organization Nordic Biosciences Clinical Development A/S ("NBCD") and is expected to enroll its first patient in the third quarter of 2021.

"Authorization of our CTA in Denmark is an important step for the Company and EP-104IAR," said Dr. James Helliwell, CEO of Eupraxia. "As this trial gets underway, we are also working to broaden the potential of this candidate by initiating a pre-clinical study to support repeat dosing. Our existing preclinical cartilage sparing data, combined with the potential for repeat dosing, are meaningful competitive differentiators that could support market expansion opportunities for EP-104IAR, if approved."

Eupraxia's Phase 2 study is a placebo-controlled, double-blind, randomized trial evaluating the efficacy and safety of EP-104IAR in 300 patients with chronic knee OA. Patients will be randomized to receive either a single injection of 25 mg EP-104IAR or placebo with a primary endpoint of change in Western Ontario and McMaster Universities Osteoarthritis Index ("WOMAC") pain score at week 12. Secondary endpoints include change in WOMAC function at week 12 and change in WOMAC pain score at week 24. There are additional endpoints relating to quality of life, disease state and use of rescue medication.

NBCD has a proven track record in conducting OA clinical trials and will initiate the trial at multiple clinical research centres in Denmark in the third quarter of 2021, with patient recruitment continuing through spring 2022, and data readout expected in the fourth quarter of 2022.

Eupraxia has an open Investigational New Drug ("IND") Application with the United States Food and Drug Administration ("FDA") and NBCD maintains a global operational footprint, allowing Eupraxia to potentially expand both the current and future trials into the United States and other geographies as necessary.

About EP-104IAR

Eupraxia's lead product candidate, EP-104IAR, is designed to meet the significant unmet medical need and market demand for long-lasting pain relief for knee OA. The U.S. Centers for Disease Control and Prevention estimates that knee OA affects more than 30 million people in the U.S. alone. This includes 14 million that suffer with knee pain or some form of disability. Knee OA is also associated with depression and loss of sleep, which can greatly affect quality of life.

With EP-104IAR, Eupraxia hopes to change the way knee OA pain is treated. Current therapies are challenged by poor safety, inadequate efficacy and/or limited duration of activity. Corticosteroids are one of only two drug classes strongly recommended by the American College of Rheumatology and the Arthritis Foundation for the treatment of knee OA pain. Currently approved corticosteroids are very effective at reducing pain for a short duration but can expose the body to unwanted local and systemic side effects.

EP-104IAR is being developed to provide long-term pain relief with fewer unwanted side effects. It encapsulates a highly potent corticosteroid (fluticasone propionate) within a microns-thin polymer membrane.

Injected into the knee, EP-104IAR is intended to slowly release drug at therapeutic concentrations for up to six months. This has the potential dual advantage of providing long-duration pain relief with fewer systemic side effects. An enhanced safety profile would also benefit the estimated 70% of knee OA patients that experience pain in both knees.

EP-104IAR has completed a Phase 1 trial and is currently in Phase 2 clinical development. A modified version of EP-104IAR is under development for canine and equine OA.

About Eupraxia

Eupraxia is a clinical-stage biotechnology company focused on the development of locally delivered, extended-release alternatives to currently approved drugs. Each of Eupraxia's product candidates has the potential to address therapeutic areas with high unmet

medical need and strives to provide improved patient benefit by delivering targeted, long-lasting activity with fewer side effects.

Eupraxia's lead product candidate, EP-104IAR, is currently in Phase 2 development for the treatment of pain due to OA of the knee. In addition to EP-104IAR, Eupraxia is developing a pipeline of earlier-stage long-acting formulations. Potential pipeline candidates include a range of drugs for indications such as post-surgical pain (EP-105), and post-surgical site infections (EP-201), each designed to improve on the activity and tolerability of approved drugs. Eupraxia is also developing a formulation of EP-104IAR for use in canine and equine OA.

For further details about Eupraxia, please visit the Company's website at: www.eupraxiapharma.com

Notice Regarding Forward-looking Statements and Information:

This news release includes forward-looking statements and forward–looking information within the meaning of Canadian securities laws. Often, but not always, forward–looking information can be identified by the use of words such as "plans", "is expected", "expects", "scheduled", "intends", "contemplates", "anticipates", "believes", "proposes" or variations (including negative and grammatical variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. Forward looking statements in this press release include statements regarding the Company's business strategies and objectives, including current and future plans and the Company's ability to move into Phase 3 development, expectations and intentions, statements regarding the Company's Phase 2 clinical trial, including the expected timing of the data readout and the results thereof, the ability of the Company to execute on its business strategy, the Company having sufficient resources, the potential of Eupraxia's product candidates, the potential for the Company's technology to impact the drug delivery process, the competitive advantages of the Company's technology, the benefits to patients from the Company's drug platforms, the translation of the Company's technologies and expansion of its offerings into clinical applications, the Company's estimation of potential product markets and the demand and market acceptance for products developed by the Company. Such statements and information are based on the current expectations of Eupraxia's management, and are based on assumptions, including but not limited to: future research and development plans for the Company proceeding substantially as currently envisioned; industry growth trends, including with respect to projected and actual industry sales; the Company's ability to obtain positive results from the Company's research and development activities, including clinical trials; and the Company's ability to protect patents and proprietary rights. Although Eupraxia's management believes that the assumptions underlying these statements and information are reasonable, they may prove to be incorrect. The forward–looking events and circumstances discussed in this news release may not occur by certain dates or at all and could differ materially as a result of known and unknown risk factors and uncertainties affecting Eupraxia, including, but not limited to: the Company's limited operating history; the Company's novel technology with uncertain market acceptance; if the Company breaches any of the agreements under which it licenses rights to its product candidates or technology from third parties, the Company could lose license rights that are important to its business; the Company's current license agreement may not provide an adequate remedy for its breach by the licensor; the Company's technology may not be successful for its intended use; the Company's future technology will require regulatory approval, which is costly and the Company may not be able to obtain it; the Company may fail to obtain regulatory approvals or only obtain approvals for limited uses or indications; the Company completely relies on third parties to provide supplies and inputs required for its products and services; the Company relies on external contract research organizations to provide clinical and nonclinical research services; the Company may not be able to successfully execute its business strategy; the Company will require additional financing, which may not be available; any therapeutics the Company develops will be subject to extensive, lengthy and uncertain regulatory requirements, which could adversely affect the Company's ability to obtain regulatory approval in a timely manner, or at all; the impact of the COVID-19 pandemic on the Company's operations; and other risks and uncertainties described in more detail in Eupraxia's public filings on SEDAR (www.sedar.com). Although Eupraxia has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward–looking statements and information, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. No forward–looking statement or information can be guaranteed. Except as required by applicable securities laws, forward–looking statements and information speak only as of the date on which they are made and Eupraxia undertakes no obligation to publicly update or revise any forward–looking statement or information, whether as a result of new information, future events or otherwise.

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