



Eupraxia's DiffuSphere™ Technology Demonstrates Targeted Drug Release while Minimizing Systemic Exposure for a Period of More Than Six Months

November 20, 2024

- DiffuSphere™ is designed to enable precise drug delivery at therapeutic dose levels directly into target tissues, enhancing efficacy while minimizing systemic drug levels to optimize safety
- In clinical trials, a single administration of DiffuSphere™ successfully delivered fluticasone propionate for at least six months in patients with eosinophilic esophagitis or osteoarthritis
- DiffuSphere™ has shown its versatility with various drug classes, supporting the possibility to treat multiple types of pain, infectious diseases, eye diseases and cancers

VICTORIA, BC, Nov. 20, 2024 /CNW/ - Eupraxia Pharmaceuticals Inc. ("Eupraxia" or the "Company") (NASDAQ: EPRX) (TSX: EPRX), a clinical-stage biotechnology company, today unveiled new pharmacokinetic ("PK") data from its Phase 2a Eosinophilic Esophagitis ("EoE") program. Management believes these data underscore the unique capabilities of Eupraxia's proprietary DiffuSphere™ platform technology, which aims to provide precise, localized, safe, and effective long-lasting drug delivery.



Most conventional drugs release in a pattern characterized by steep peaks and rapid declines in drug concentration, where peaks often lead to negative side effects, and troughs result in reduced efficacy. In contrast, DiffuSphere™ is a unique microsphere that is designed to enable precise drug release into target tissues with a flat, stable, and long-lasting profile, minimizing potential adverse events associated with high-dose systemic delivery.

What sets DiffuSphere™ apart is its composition: a pure drug crystal encased in a microns-thick polymer shell. Eupraxia's proprietary technology uses this polymer to precisely control a drug's release, ensuring high drug concentrations in the target tissues while minimizing exposure to the rest of the body. This innovative approach has been observed in Eupraxia's clinical programs, demonstrating precision, tolerability, and extended duration of delivering fluticasone propionate ("FP") directly to the intended tissues for EoE and knee osteoarthritis ("OA") patients.

"Our DiffuSphere™ platform is designed to enable us to deliver the right drug to the right place at the right time with a precise PK profile, aiming to ensure patients receive safe, effective, and durable treatment," said Eupraxia's CEO, Dr. James Helliwell. "We

are excited about the broad-based potential of DiffuSphere™. The clinical data from EoE and OA, combined with our extensive non-clinical data showing precise delivery of numerous drugs in a broad array of target tissues, reinforces our optimism."

RESOLVE Trial Demonstrates Compelling Pharmacokinetics in the Esophagus

DiffuSphere™, when injected into the esophageal wall (submucosa), shows a treatment duration exceeding six months from a single injection, with predictable dose control. In Cohort 1 (4 mg FP), a steady level of 1.5 pg/ml was maintained for at least six months. In Cohort 5 (48 mg FP), 10pg/ml was observed at three months. With this steady, localized, and long-lasting delivery, key EoE disease measures, including patient symptoms, esophageal tissue health, and eosinophil counts, improved. This impact of the DiffuSphere™ technology was clearly demonstrated in a non-clinical study in pigs comparing local and systemic levels of FP after intraesophageal injection of EP-104GI versus oral gavage. Presented at the American College of Gastroenterology meeting ([poster](#)), the study revealed that esophageal tissue levels of fluticasone were more than 1000 times higher in the EP-104GI group compared to the oral gavage group, even at distances of several centimeters from the injection sites. Moreover, despite significantly higher local concentrations, systemic levels of fluticasone in the plasma were lower in the EP-104GI group than in the oral gavage group. This underscores the targeted and precise delivery capabilities of the DiffuSphere™ technology.

DiffuSphere™ in the Joint

DiffuSphere™ is the technology behind Eupraxia's EP-104IAR for treating OA. In Eupraxia's Phase 2b clinical study, EP-104IAR was well tolerated and showed significantly durable efficacy over placebo. The trial results were recently published in [The Lancet](#), reinforcing the preclinical work previously published in [Cartilage](#). The Phase 2b data showed that EP-104IAR effectively controlled patients' pain for up to 22 weeks (as measured by OARSI Strict Responders) and was well-tolerated. This includes no disruption to blood glucose metabolism (a key factor for diabetics, who comprise almost 40% of the OA population) or adrenal function, which have been reported with other steroid formulations used in this indication.

DiffuSphere™ in Other Applications

Eupraxia has successfully applied DiffuSphere™ across multiple anatomic locations and drug classes. In preclinical studies, DiffuSphere™ has demonstrated its precise, steady, and tunable delivery traits in intraarticular, intraesophageal, intravitreal, epidural, peritoneal, and subcutaneous applications. Additionally, Eupraxia has demonstrated DiffuSphere's™ capability with local anesthetics such as ropivacaine and various anti-infective agents.

The new data in EOE patients further supports DiffuSphere's™ ability to deliver drugs with local precision: stable drug delivery without peaks and troughs, and a customizable duration to fit the clinical indication. This reinforces Eupraxia's confidence in the platform's broad potential.

About Eosinophilic Esophagitis (EOE) and the RESOLVE Trial

EoE is an inflammatory-mediated disease in which white blood cells migrate into and become trapped in the esophagus, creating pain and difficulty with swallowing food. According to market research from Clearview Healthcare Partners, EoE affects more than 450,000 people in the United States and has been identified by the American Gastroenterological Association as rapidly increasing in both incidence and prevalence. Impacts from both symptoms and interventions frequently lead to mental health issues, compounding the disease burden of EoE for both the healthcare system and the individual.

RESOLVE is a Phase 1b/2a, multicenter, open-label, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of EP-104GI in adults with histologically confirmed, active EoE. EP-104GI is administered as a single dose via four to 20 injections into the esophageal wall. Dose escalations increase the dose per site and/or number of sites. Participants in the first through the fourth cohorts will be assessed for up to 24 weeks, and cohorts five and above will be assessed for up to 52 weeks.

About Osteoarthritis (OA)

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

With EP-104IAR, Eupraxia hopes to change the way knee OA pain is treated. The Company believes 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 treating knee OA pain. Currently approved corticosteroids are very effective at reducing pain for a short duration late in the disease but can expose the body to unwanted local and systemic side effects.

EP-104IAR is designed to prolong the duration of pain relief with fewer adverse events. It encapsulates a highly potent corticosteroid (fluticasone propionate) within a microns-thin polymer membrane, part of Eupraxia's patented technology platform.

Injected into the knee, EP-104IAR is designed to diffuse the corticosteroid slowly into the knee joint providing local therapeutic concentrations for up to six months. This has the potential dual advantage of providing longer duration of pain relief with fewer systemic adverse events. A robust safety and tolerability profile would also benefit the estimated 70% of knee OA patients that

experience pain in both knees by allowing simultaneous treatment of both affected joints. EP-104IAR has also been designed to incorporate additional advantages, such as physician convenience, targeting a long shelf life, no refrigeration and easy integration into existing delivery techniques.

About Eupraxia Pharmaceuticals Inc.

Eupraxia is a clinical-stage biotechnology company focused on developing locally delivered, extended-release products that have the potential to address therapeutic areas with high unmet medical need. DiffuSphere™, a proprietary, polymer-based micro-sphere technology, is designed to facilitate targeted drug delivery of both existing and novel drugs. The technology is designed to support extended duration of effect and delivery of drugs in a hyper-localized fashion, targeting only the tissues that physicians are wanting to treat. We believe the potential for fewer adverse events may be achieved through the precision targeting and the stable and flat delivery of the active ingredient when using the DiffuSphere™ technology, versus the peaks and troughs seen with more traditional drug delivery methods. The precision of Eupraxia's DiffuSphere™ technology platform has the potential to augment and transform existing FDA-approved drugs to improve their safety, tolerability, efficacy and duration of effect. The potential uses in therapeutic areas may go beyond pain and inflammatory gastrointestinal disease, where Eupraxia currently is developing advanced treatments, to also be applicable in oncology, infectious disease and other critical disease areas.

Eupraxia's EP-104GI is currently in a Phase 1b/2a trial, the RESOLVE trial, for the treatment of EoE. EP-104GI is administered as an injection into the esophageal wall, providing local delivery of drug. This is a unique treatment approach for EoE. Eupraxia also recently completed a Phase 2b clinical trial (SPRINGBOARD) of EP-104IAR for the treatment of pain due to knee osteoarthritis. The trial met its primary endpoint and three of the four secondary endpoints. In addition, Eupraxia is developing a pipeline of later and earlier-stage long-acting formulations. Potential pipeline indications include candidates for other inflammatory joint indications and oncology, each designed to improve on the activity and tolerability of currently approved drugs. 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 applicable securities laws. Often, but not always, forward-looking information can be identified by the use of words such as "plans", "is expected", "expects", "aims", "suggests", "scheduled", "intends", "contemplates", "anticipates", "believes", "proposes", "potential" 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 news release include statements regarding the Company's product candidates, including their expected benefits to patients with respect to safety, tolerability, efficacy and duration; additional clinical data from the RESOLVE trial of EP-104GI in EoE, including the Company's intention to periodically disclose such data and timing thereof; the Company's expectations regarding dose-escalating cohorts; the results gathered from studies and trials of Eupraxia's product candidates; the potential for the Company's technology to impact the drug delivery process; potential market opportunity for the Company's products; and potential pipeline indications. 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: risks and uncertainties related 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's clinical trials may fail to demonstrate adequately the safety and efficacy of its product candidates at any stage of clinical development; the Company may be required to suspend or discontinue clinical trials due to side effects or other safety risks; 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 non-clinical 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 health pandemics or epidemics on the Company's operations; the Company's restatement of its consolidated financial statements, which may lead to additional risks and uncertainties, including loss of investor confidence and negative impacts on the Company's common share price; and other risks and uncertainties described in more detail in Eupraxia's public filings on SEDAR+ (sedarplus.ca) and EDGAR (sec.gov). 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.

View original content to download multimedia: <https://www.prnewswire.com/news-releases/eupraxias-diffusphere-technology-demonstrates-targeted-drug-release-while-minimizing-systemic-exposure-for-a-period-of-more-than-six-months-302311140.html>

SOURCE Eupraxia Pharmaceuticals Inc.