Eupraxia Pharmaceuticals Announces Expansion of RESOLVE Phase 1b/2a Trial of EP-104GI for Treatment of Eosinophilic Esophagitis

- Eight of nine patients responding to the treatment, plus the encouraging safety data observed in the RESOLVE Phase 1b/2a trial of EP-104GI, provided the catalyst for the trial expansion
- Early low-dose cohorts showing meaningful improvement in patient symptoms and biological evidence of disease
- Trial expansion allows more patients to be treated at higher doses and followed for up to 52 weeks, up from 24 weeks

Victoria, B.C. – May 23, 2024 – Eupraxia Pharmaceuticals Inc. ("Eupraxia" or the "Company") (TSX: EPRX) (NASDAQ: EPRX), a clinical-stage biotechnology company leveraging its proprietary DiffuSphere™ technology to optimize drug delivery for applications with significant unmet need, today announced that regulators in Australia and Canada have cleared the Company's request to expand its Phase 1b/2a RESOLVE trial, which is evaluating the safety and efficacy of EP-104GI as a treatment for eosinophilic esophagitis ("EoE").

The recently disclosed clinical data from initial low-dose cohorts showing signs of potential efficacy, as well as encouraging safety and duration of impact from EP-104GI, support the significant expansion of the RESOLVE trial as a pathway to a potential registration trial commencing in 2025.

"We are excited about the data to date from the RESOLVE trial, particularly the patient responses and the extended duration of effect," said Dr. James Helliwell, Chief Executive Officer of Eupraxia. "Our DiffuSphere™ delivery technology is a supporting factor for this opportunity for higher dosing, which could result in a longer duration of efficacy and more profound patient improvement. We believe that the encouraging data seen in patients in our lowest-dose cohorts opens the door, with this amendment, to develop a potentially efficacious annual therapy with a strong safety profile for patients suffering with EoE."

The Company intends to continue to periodically disclose additional data from the trial.

Protocol Amendment Cleared By Regulators

Based on the promising data collected from the RESOLVE trial to date, the Company has expanded the Phase 1b/2a study to continue evaluating the safety and efficacy of EP-104GI at higher doses, with a longer duration of follow-up, in more participants. A protocol amendment has already been cleared by the Australian Health Authority and Health Canada. The protocol amendment for trial expansion includes:

- The addition of 4 mg/injection site and 6 mg/injection site doses and an option of up to 20 injections for dose escalation. Based on safety, pharmacokinetic, and efficacy observations in cohorts one through three, higher dose levels could potentially demonstrate a greater benefit of treatment with a longer duration of effect.
- An increase in the number of participants planned from 12-15 to 27-33, reflecting the increase in possible dose levels to be explored.
- Enrolment of an additional 10-24 participants in one or two dose confirmation cohorts, to more thoroughly evaluate safety and efficacy of EP-104GI in EoE at the doses identified during the dose escalation stage as being likely candidates for future clinical development.
- To evaluate the potentially longer duration of effect of EP-104GI at higher doses, the study follow-up was extended from 24 weeks to 52 weeks for participants who receive doses of >40 mg (total dose) of EP-104GI.
- The addition of an esophagogastroduodenoscopy procedure with esophageal biopsies at week 36 for participants who receive doses >40 mg of EP-104GI to evaluate the potentially longer duration of effect of EP-104GI at higher doses.

Additional clinical sites will be added in current jurisdictions to support the new recruitment target, and site feasibility has commenced to open additional geographic regions as needed to support the trial expansion.

Encouraging Data from the RESOLVE Trial Provides the Catalyst for the Protocol Amendment

The Company's recently disclosed data from the RESOLVE study have provided a catalyst to amend the protocol for the trial.

The results announced on May 21, 2024, from the first three cohorts of the RESOLVE trial, using Eupraxia's Diffusphere™ technology for EoE, show:

- Patients are seeing a clinically meaningful symptom response for as long as they have been followed as measured by Strauman Dysphagia Index (SDI) (24 weeks for cohorts one and two).
- Through the dose escalation of the first three cohorts, the biological response as seen in Peak Eosinophil Scores (PEC) and Eosinophilic Esophagitis Histology Scores (EoEHSS) has increased.

About EoE

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, 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 health care system and the individual.

About the RESOLVE Trial

RESOLVE is a Phase 1b/2a, multicentre, 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 Eupraxia Pharmaceuticals Inc.

Eupraxia is a clinical-stage biotechnology company focused on the development of locally delivered, extended-release products that have the potential to address therapeutic areas with high unmet medical need. The Company strives to provide improved patient benefit and has developed technology designed to deliver targeted, long-lasting activity with fewer side effects. DiffuSphere™, a proprietary, polymer-based micro-sphere technology, is designed to facilitate targeted drug delivery, with extended duration of effect, and offers multiple, highly tuneable pharmacokinetic (PK) profiles. This investigational technology can be engineered for use with multiple active pharmaceutical ingredients and delivery methods.

Eupraxia recently completed a Phase 2b clinical trial (SPRINGBOARD) of EP-104IAR for the treatment of pain due to osteoarthritis of the knee. The trial met its primary endpoint and three of the four secondary endpoints. Eupraxia has expanded the EP-104 platform into gastrointestinal disease with the Phase 1b/2a RESOLVE trial for treating EoE. Eupraxia is also 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", “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 additional clinical data from the RESOLVE trial of EP-104GI in EoE, including the Company’s intention to periodically disclose such data; the potential to extend periods between intra-esophageal injections; the filing of protocol amendments to expand the RESOLVE trial, including higher dose levels and increased number of participants; the Company's product candidates, including expected benefits to patients with respect to safety, efficacy and duration; 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 our 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.

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