

# **Ipsen Completes Acquisition of Clementia Pharmaceuticals**

- Ipsen's Rare Diseases portfolio significantly enhanced with late-stage drug candidate, palovarotene, for the treatment of rare bone disorders in adult and pediatric patients
- Transaction reinforces Ipsen's strong commitment to providing life-altering treatments to patients with high unmet medical needs

Paris, 18 April 2019 – Ipsen (Euronext: IPN; ADR: IPSEY) and Clementia Pharmaceuticals (NASDAQ: CMTA) today announced the closing of Ipsen's acquisition of Clementia following approval of the arrangement by Clementia shareholders and the Quebec Superior Court. Pursuant to the arrangement, Clementia shareholders will receive US\$25.00 per share in cash upfront and one contingent value right (CVR) per share entitling them to receive US\$6.00 per CVR upon the U.S. Food and Drug Administration's (FDA) acceptance of the regulatory filing for palovarotene for the treatment of multiple osteochondromas (MO).

Clementia's key late-stage clinical asset palovarotene is an investigational retinoic acid receptor gamma (RARy) selective agonist, for the treatment of two rare bone disorders, fibrodysplasia ossificans progressiva (FOP) and multiple osteochondromas (MO), and other diseases.

The palovarotene regulatory submission for the prevention of heterotopic ossification (HO) in patients with FOP in the U.S. is expected for the second half of 2019. The submission will be based on Phase 2 clinical data from greater than 100 imaged flare-ups and indicated that treatment with palovarotene resulted in a greater than 70% reduction of new heterotopic ossification (HO), or bone formation, across all three dosing levels.

**Dr. Alexandre Lebeaut, Chief Scientific Officer of Ipsen**, commented, "We are encouraged by compelling and consistent clinical data from the extensive Phase 2 program as well as fast-track, breakthrough therapy, orphan drug and rare pediatric diseases designations from the FDA. We are focused on the successful regulatory submission of palovarotene as a first-inclass therapeutic solution for patients with episodic flare-up treatment of fibrodysplasia ossificans progressiva in the second half of 2019."

**Dr. Clarissa Desjardins, Chief Executive Officer of Clementia**, added, "I am extremely grateful for the hard-working and dedicated team at Clementia, the patient community and the clinical trial investigators who have helped advance the palovarotene program. Going forward, we are confident that Ipsen, with its shared patient-centric culture, proven development

capabilities and global commercial footprint, will fulfill our ambition of delivering palovarotene to patients worldwide as quickly as possible."

#### About Fibrodysplasia Ossificans Progressiva (FOP)



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FOP is an ultra-rare, severely disabling disorder characterized by heterotopic ossification (HO), or bone that forms outside the normal skeleton, in muscles, tendons or soft tissue. In FOP, HO progressively restricts movement by locking joints, leading to a cumulative loss of function, progressive disability, and increased risk of early death. FOP is caused by a mutation in the ACVR1 gene, resulting in excess signaling in the bone morphogenetic pathway, a key pathway controlling bone growth and development, by way of both ligand-dependent and independent mechanisms. The prevalence of FOP is approximately 1.3 individuals per million lives, or approximately 9,000 patients globally. There are currently no approved treatments for FOP.

## **About Multiple Osteochondromas (MO)**

MO, also called multiple hereditary exostoses (MHE) is a rare, severely disabling, progressive, chronic disease in which multiple benign bone tumors, also known as osteochondromas (OCs) or osteocartilaginous exostoses, develop on bones. MO is typically diagnosed in early childhood when OCs become visible with a median age at diagnosis of four years. Because of their development around joints, children develop limb deformity and restricted movement as they grow. Today, the only available treatments for MO are surgery and palliative care, and many patients will undergo surgery, some as many as 30 surgeries, before adulthood. MO is estimated to affect 20 individuals per million lives, or approximately 150,000 globally. MO is among the most common inherited bone disorders with multiple family members in multiple generations affected.

#### **About Palovarotene**

Palovarotene is an RARγ agonist being developed as a treatment for patients with ultra-rare/rare and debilitating bone diseases, including fibrodysplasia ossificans progressiva (FOP) and multiple osteochondromas (MO), as well as other diseases. Palovarotene was in-licensed from Roche Pharmaceuticals, where it was previously evaluated in more than 800 subjects, including 450 patients treated for up to two years. Palovarotene has received Orphan Drug status for FOP and MO from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). In addition, palovarotene has been granted Fast Track, Breakthrough Therapy and Rare Pediatric Disease designations for FOP from the FDA.

## **About Ipsen**

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neuroscience and Rare Diseases. Its commitment to Oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales over €2.2 billion in 2018, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,700 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit www.ipsen.com.

## **About Clementia Pharmaceuticals Inc.**

Clementia is a clinical-stage company innovating treatments for people with ultra-rare bone disorders and other diseases with high medical need. The company is preparing for a 2019 new drug application (NDA) submission to the FDA to seek approval of its lead product candidate, palovarotene, a novel RARy agonist, for the prevention of heterotopic ossification (HO) associated with flare up symptoms in adults and children with fibrodysplasia ossificans progressiva (FOP). The ongoing Phase 3 MOVE Trial is evaluating an additional dosing regimen of palovarotene for the treatment of FOP. Palovarotene is also in a Phase 2 trial, the MO-Ped Trial, for the treatment of multiple osteochondromas (MO, also known as multiple hereditary exostoses, or MHE). In addition, Clementia has commenced a Phase 1 trial for an eye drop formulation of palovarotene for the potential treatment of dry eye disease and is also investigating other conditions that may benefit from RARy therapy. For more information, please

visit www.clementiapharma.com and connect with us on Twitter @ClementiaPharma.

#### **Forward Looking Statement**

This press release may include "forward-looking statements" within the meaning of the applicable securities laws, including with respect to the proposed timing of filings and submissions with the FDA for palovarotene and the impact of the transaction on Ipsen and Clementia, the operations of Ipsen and Clementia post-transaction and the amounts potentially payable under the CVRs. Each forward-looking statement contained in this press release is subject to known and unknown risks and uncertainties and other unknown factors that could cause actual results to differ materially from historical results and those expressed or implied by such statement. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labeled with the terms "believes," "belief," "expects," "intends," "anticipates," "will," or "plans" to be uncertain and forwardlooking. Applicable risks and uncertainties include, among others, the outcome of the FDA approval of palovarotene product candidate for the treatment of multiple osteochondromas (MO), Clementia's ability to successfully complete in a timely manner the studies required to be completed in order to submit the NDA, Clementia's ability to generate revenue and become profitable, the risks related to its heavy reliance on palovarotene, its only current product candidate, the risks associated with the development of palovarotene and any future product candidate, including the demonstration of efficacy and safety, Ipsen's and Clementia's dependence on licensed intellectual property, including the ability to source and maintain licenses from third-party owners; as well as the risks identified in Ipsen's registration documents filed with the French Autorité des Marchés Financiers and Clementia's public filings with the SEC and the Québec Autorité des Marchés Financiers. Ipsen and Clementia caution investors not to rely on the forward-looking statements contained in this press release when making an investment decision in their securities. Investors are encouraged to read Ipsen's filings available on its website (www.ipsen.com) as well as Clementia's filings with the SEC or on SEDAR, available at www.sec.gov or www.sedar.com, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this press release, and Ipsen and Clementia undertake no obligation to update or revise any of these statements, whether as a result of new information, future events or otherwise, except as required by law.

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