

# Cosmo sub-licenses its ByFavo™ (Remimazolam) US rights to Acacia Pharma, takes an initial 14.1% stake and provides finance for Acacia Pharma's US expansion

**Dublin, Ireland – January 10, 2020** - Cosmo Pharmaceuticals N.V. (SIX: COPN) today announced that it has sublicensed its ByFavo US rights to Acacia Pharma Group plc (ENX: ACPH) and acquired an initial 14.1% stake in it, whilst providing financing to further Acacia Pharma's US expansion.

In 2016, Cosmo acquired from Paion AG (FWB: PA8) for € 10 million the exclusive US rights for the development and commercialization of ByFavo (Remimazolam), an ultrashort-acting intravenous benzodiazepine sedative/ anaesthetic that has shown positive results in clinical Phase III trials. In anticipation of the PDUFA date set for April 5, 2020, Cosmo has thus secured the commercial partner for the marketing and distribution of ByFavo in the US in the context of its equity-for-product strategy.

Acacia Pharma is a pharmaceutical company focused on the development and commercialization of new nausea and vomiting treatments for surgical and cancer patients. Acacia Pharma is based in Cambridge, UK and Indianapolis, IN (USA) and its shares are listed on Euronext - Brussels. Acacia Pharma's lead project is BARHEMSYS® (intravenous amisulpride), which has achieved very positive results in four Phase III clinical studies in post-operative nausea and vomiting (PONV). The NDA for BARHEMSYS has been filed and target PDUFA date is February 26, 2020. Acacia Pharma has set up a commercial organization in the US which will have its footprint in hospitals and Ambulatory Surgical Centres (ASC), the same calling points of ByFavo.

Cosmo at signing will receive a € 10 million upfront payment in Acacia Pharma shares and will make a € 10 million investment in Acacia Pharma shares, thus becoming a 14.1% shareholder with right to one seat on the Acacia Pharma Board of Directors. Cosmo will further receive € 20 million in Acacia Pharma shares at ByFavo approval and first sales, thus increasing its stake, plus up to USD 105 million in commercial ByFavo milestones and the same royalties Cosmo owes to Paion. Cosmo will also grant a first loan of € 10 million upon approval of BARHEMSYS and a second loan of € 25 million upon approval of ByFavo at market terms.

Alessandro Della Chà, CEO of Cosmo, said: "It took us more than six months of hard work to find the best possible US partner for ByFavo, following the same pattern as the RedHill transaction. We came to the conclusion that ByFavo, as much as Aemcolo, can better and faster achieve its sales potential within an organization with multiple products in the same market and significant commercial expertise. If approved, both ByFavo and BARHEMSYS will share not only the same calling points but also the same commercial message in reducing procedure time and hospitalization. The deal gives Acacia Pharma the necessary means to boost its business focused on hospitals and ASC sales in the US and provides critical financing to accelerate its growth. This

transaction is therefore consistent with our strategy to bundle our products into small and focussed companies in which we can have substantial equity stakes to participate in the potential growth in value. I am very satisfied by this synergy and I trust Acacia Pharma, with the help of Cosmo, will deliver the right reward both to its shareholders and to Paion as licensor, of which Cosmo continues holding the major stake."

Mike Bolinder, CEO of Acacia Pharma, said: "We are delighted to have in-licensed ByFavo, which provides an excellent complementary product opportunity to BARHEMSYS. Having a second product that shares the same calling points and commercial message will make the investment in our sales and marketing teams far more efficient in delivering better options for physicians and patients. The equity investment from Cosmo is a great validation of Acacia Pharma and strengthens our balance sheet as we move towards the PDUFA date for BARHEMSYS, which is targeted for 26 February 2020. The availability of debt finance is also important as it will allow us to invest in the anticipated launch and commercialisation of BARHEMSYS and subsequently in ByFavo. I am sure we have found in Cosmo the right partner for our future expansion."

Jefferies acted as exclusive financial adviser to Cosmo in connection with this transaction.

### **About Cosmo Pharmaceuticals**

Cosmo is a specialty pharmaceutical company focused in treating selected Gastrointestinal Disorders and Endoscopy. The Company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, Colonic Infections and detection of colonic lesions. Cosmo has also developed medical devices for endoscopy and has recently entered into a partnership with Medtronic for the global distribution of its novel Artificial Intelligence device to be used in colonoscopies and GI procedures. Further, Cosmo is the licensee for US of the novel agent for procedural sedation, ByFavo (Remimazolam). For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

# **About Acacia Pharma**

Acacia Pharma is a hospital pharmaceutical company focused on the development and commercialization of new nausea and vomiting treatments for surgical and cancer patients. The Group has identified important and commercially attractive unmet needs in nausea & vomiting and has discovered two product candidates based on the same active ingredient, amisulpride, to meet those needs.

The Group's lead project, BARHEMSYS® (intravenous amisulpride) for post-operative nausea & vomiting (PONV), has generated positive results in four Phase III clinical studies. Its sister project, APD403 for chemotherapy induced nausea and vomiting (CINV), has successfully completed one proof-of-concept and one Phase II dose-ranging study in patients receiving highly emetogenic chemotherapy.

Acacia Pharma is based in Cambridge, UK and Indianapolis, IN. The Company is listed on the Euronext Brussels exchange under the under ISIN code GB00BYWF9Y76 and ticker symbol ACPH. www.acaciapharma.com

## Cosmo Pharmaceuticals Calendar

FY 2019 Results Annual General Meeting 2020 April 3, 2020 May 28, 2020

#### Contact:

Niall Donnelly, Chief Financial Officer & Head of Investor Relations Cosmo Pharmaceuticals N.V.

Tel: +353 1 817 03 70

ndonnelly@cosmopharma.com

Some of the information contained in this press release contains forward-looking statements. Readers are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those in the forward-looking statements as a result of various factors. Cosmo undertakes no obligation to publicly update or revise any forward-looking statements.

This communication is not an offer of securities of any issuer. Securities may not be offered or sold in the United States absent registration or an exemption from the registration requirement of the US Securities Act of 1933.

This press release constitutes neither an offer to sell nor a solicitation to buy securities and it does not constitute a prospectus within the meaning of article 652a and/or 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or any similar document. The offer will be made solely by means of, and on the basis of, a securities prospectus to be published. An investment decision regarding the securities to be publicly offered should only be made on the basis of the securities prospectus.

This press release is made to and directed only at (i) persons outside the United Kingdom, (ii) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"), and (iii) high net worth individuals, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order. Any person who is not a relevant person should not act or rely on this press release or any of its contents.

This press release does not constitute an "offer of securities to the public" within the meaning of Directive 2003/71/EC of the European Union (the "Prospectus Directive") of the securities referred to in it (the "Securities") in any member state of the European Economic Area (the "EEA"). Any offers of the Securities to persons in the EEA will be made pursuant to an exemption under the Prospectus Directive, as implemented in member states of the EEA, from the requirement to produce a prospectus for offers of the Securities.