Cosmo announces successful Phase III clinical trial of Lumeblue™ in China

Dublin, Ireland – 14 December 2022: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) ("Cosmo") today announced the successful phase III clinical trial of Lumeblue™ in China, sponsored by its partner China Medical System Holdings Limited (CMS) (867.HK).

In the trial, Lumeblue™ was compared to placebo in white light colonoscopy with the purpose of assessing its safety and efficacy in the improvement of histologically confirmed non-polypoid colorectal lesions in subjects undergoing screening or surveillance colonoscopy for colorectal cancer (CRC). The non-polypoid (i.e. flat) lesions are notoriously the most difficult to detect, and especially so when they are <10mm. In literature, data show that the miss rate (the fraction of lesions that are routinely missed) is highest among this type of lesions.

The study was a randomized, double-blind, placebo-controlled trial (placebo being in this case the standard of care) run under GCP in 22 sites across China. All patients were prepped with Fortrans 3-liter split dose, two liters the day before the procedure and one liter the day of the procedure.

In total, 1802 subjects were randomized, 897 in the Lumeblue arm and 905 in the placebo arm. Of those, 872 in the Lumeblue arm and 879 in the placebo arm were in the primary efficacy population (FAS: Full Analysis Set).

The primary endpoint of the study was the detection rate of non-polypoid colorectal lesions, defined as "*the proportion of subjects with at least one histologically confirmed non-polypoid colorectal lesion*".

The study met the primary endpoint with very high statistical significance: in the overall FAS, the proportion of patients with at least one histologically confirmed non-polypoid colorectal lesion was significantly higher in the Lumeblue group (445/872 subjects; 51.0%) as compared with placebo (362/879, 41.2%); (adjusted OR [95% CI]: 1.55 [1.27, 1.89]; P< 0.0001).

The study also confirmed the superiority of Lumeblue versus placebo in several clinically meaningful endpoints:

a) Number of histologically confirmed non-polypoid colorectal lesions per patient

In the FAS, the per patient number of histologically confirmed non-polypoid colorectal lesions in the Lumeblue group was 0.9, as compared to 0.7 in the placebo group (difference between groups [95%CI]: 0.18 [0.07, 0.30] P=0.0022).

b) Number of histologically confirmed non-polypoid adenomas or cancers per patient

In the FAS, the per patient number of histologically confirmed non-polypoid adenomas or cancers in the Lumeblue group was 0.6 as compared to 0.5 in the placebo group (difference between groups [95%CI] 0.12 ([0.03, 0.22] P=0.0125).

c) Detection rate of non-polypoid adenoma or cancer (NP-ADR)

In the FAS, 341 out of 872 patients (39.1%) were detected with at least one histologically confirmed non-polypoid adenoma in the Lumeblue arm, as compared with 274 out of 879 patients in the placebo group (31.2%) (OR [95%CI]: 1.43 [1.17, 1.75] P=0.0004).Proportion of patients with at least one histologically confirmed <10 mm non-polypoid colorectal lesion

Non-polypoid histologically confirmed colorectal lesions less than <10 mm were found in 415 out of 872 patients (47.6%) in the Lumeblue group versus 350 out of 879 patients (39.8%) in the placebo group (OR [95%CI] 1.43 [1.17, 1.74] P= 0.0003).

e) Number of histologically confirmed <10 mm non-polypoid colorectal lesions per patient

In the FAS, the per patient number of histologically confirmed non-polypoid colorectal lesions <10 mm was 0.9 in the Lumeblue group versus 0.7 in the placebo group (difference between groups [95%CI]: 0.15 [0.03, 0.26] P=0.0110).

f) Number of histologically confirmed non-polypoid adenomas or cancers <10 mm per patient

Overall, the per patient number of histologically confirmed non-polypoid adenomas or cancers <10 mm was 0.6 in the Lumeblue test group versus 0.5 in the placebo group (difference between groups [95 %CI]: 0.11 [0.02, 0.20] P=0.0199).

No severe side effects were reported.

Mr. Yin, Director of Medical Department of CMS, said: "*These excellent results showed that Lumeblue tablets could significantly improve the detection rate of non-polypoid lesions including non-polypoid adenoma or cancer during standard colonoscopy. Lumeblue, if approved by the competent authority, will potentially benefit millions of people who get colonoscopies in China. We see Lumeblue as a compelling opportunity*".

Alessandro Della Chà, CEO of Cosmo Pharma, said: "*We are very thankful to our partner CMS for this great clinical outcome, which is in line with our expectations and further confirms the data coming from our prior trial. Lumeblue has proven once again its capacity of helping, in particular, the detection of the <10mm flat lesions, which are the most dangerous, and its efficacy also with the split dose prep regimen. We are thus very much looking forward to bring Lumeblue in the Chinese market, which is the largest colonoscopy market of all*".

About Cosmo

Cosmo is a pharmaceutical company focused on developing and commercialising products to treat selected gastrointestinal disorders, to improve endoscopy quality measures through aiding the detection of colonic lesions and to treat selected dermatological conditions. Cosmo develops and manufactures products which are distributed globally by selected partners including Lialda®, Uceris®/Cortiment® and Winlevi®. Cosmo has also developed medical devices for endoscopy and has a partnership with Medtronic for the global distribution of GI Genius™ which uses artificial intelligence to help detect potential signs of colon cancer. Cosmo has licensed Aemcolo® to Red Hill Biopharma Ltd. for the US and has licensed Relafalk® to Dr. Falk Gmbh for the EU and other countries. The company also has a rich development pipeline. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

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