NOTICE TO THE MARKET
GRUPO BIOTOSCANA ANNOUNCES NEW APPROVALS

BIOTOSCANA INVESTMENTS S.A. ("Company" or "GBT") (B3: GBIO33), a leading biopharmaceutical company in Latin America, announces to its shareholders and the market in general that it has received new regulatory approvals for three products – CRESEMBA® (isavuconazole), BUSILVEX® (busulfan) and AMBISOME® (amphotericin B).

The antifungal CRESEMBA® was approved by ANMAT in Argentina for the treatment of adult patients with invasive aspergillosis and for the treatment of adult patients with mucormycosis for whom amphotericin B is inappropriate. The product is a well differentiated drug that addresses a critical medical need in patients with invasive mold infections.

BUSILVEX® was approved in Chile as conditioning treatment prior to hematopoietic progenitor cell transplantation (HPCT) under three different conditions. Firstly, BUSILVEX® can be used followed by cyclophosphamide as conditioning treatment prior to HPCT in adult patients, when the combination is considered the best available option. It can also be used following fludarabine as conditioning treatment prior to HPCT in adult candidates for a reduced intensity conditioning regimen. In pediatric patients, BUSILVEX® is used followed by cyclophosphamide or melphalan.

The registration transfer of AMBISOME® was approved in Peru. AMBISOME® is approved for the empirical therapy for presumed fungal infection in febrile, neutropenic patients, treatment of Cryptococcal Meningitis in HIV infected patients, treatment of patients with Aspergillus species, Candida species and/or Cryptococcus species infections refractory to amphotericin B deoxycholate, or in patients where renal impairment or unacceptable toxicity precludes the use of amphotericin B deoxycholate and treatment of visceral leishmaniasis. GBT also holds licensing rights to AMBISOME® in Brazil, Bolivia and Paraguay.

GBT is committed to maximizing the value of our portfolio and increasing the benefits provided to patients as well as healthcare providers.
About GBT Grupo Biotoscana

GBT-Grupo Biotoscana (GBT) is a biopharmaceutical group that operates in the fast-growing Latin American region and focuses on rapidly growing market segments such as infectious diseases, oncology and onco-hematology, special treatments, immunology and inflammation and orphan/rare diseases, among others. GBT is currently present throughout 10 Latin American countries where it operates under its companies Biotoscana, United Medical, LKM and DOSA. GBT’s strong portfolio combines world-class licenses and proprietary products. To find out more, please visit www.grupobiotoscana.com.

About CRESEMBA® (isavuconazole)

Isavuconazole is an intravenous (i.v.) and oral azole antifungal and the active agent of the prodrug isavuconazonium sulfate. In the EU and EEA member states, as well as in Argentina, Jordan and Peru, it is approved for the treatment of adult patients with invasive aspergillosis and for the treatment of adult patients with mucormycosis for whom amphotericin B is inappropriate1. It is also approved in the U.S.2 and Switzerland3. Isavuconazole has U.S. and European orphan drug designation for the approved indications.

About BUSILVEX® (busulfan)

BUSILVEX® followed by cyclophosphamide (BuCy2) is indicated as conditioning treatment prior to conventional hematopoietic progenitor cell transplantation (HPCT) in adult patients when the combination is considered the best available option. BUSILVEX® following fludarabine (FB) is indicated as conditioning treatment prior to hematopoietic progenitor cell transplantation (HPCT) in adult patients who are candidates for a reduced-intensity conditioning (RIC) regimen. BUSILVEX® followed by cyclophosphamide (BuCy4) or melphalan (BuMel) is indicated as conditioning treatment prior to conventional hematopoietic progenitor cell transplantation in pediatric patients.

About AMBISOME® (amphotericin B)

AMBISOME® for Injection is a sterile, non-pyrogenic lyophilized product for intravenous infusion containing 50 mg of amphotericin B, intercalated into a liposomal membrane. AMBISOME® is a true single bilayer liposomal drug delivery system. Liposomes are closed, spherical vesicles created by mixing specific proportions of amphiphilic substances such as phospholipids and cholesterol so that they arrange themselves into multiple concentric bilayer membranes when hydrated in aqueous solutions. AMBISOME® is indicated for the empirical therapy for presumed fungal infection in febrile, neutropenic patients, treatment of Cryptococcal Meningitis in HIV infected patients, treatment of patients with Aspergillus species, Candida species and/or Cryptococcus species infections refractory to amphotericin B deoxycholate, or in patients where renal impairment or unacceptable toxicity precludes the use of amphotericin B deoxycholate and treatment of visceral leishmaniasis.

Forward-Looking Statements (GBT)

This release includes forward-looking statements concerning a transaction between GBT-Grupo Biotoscana and Basilea, including expectations regarding the applicability of predictions to the commercialization of certain products. GBT-Grupo Biotoscana disclaims any obligation to update any forward-looking statement, except as required by applicable law.

This release includes forward-looking statements concerning a transaction between GBT-Grupo Biotoscana and Gilead, including expectations regarding the applicability of predictions to the commercialization of certain products. GBT-Grupo Biotoscana disclaims any obligation to update any forward-looking statement, except as required by applicable law.

This release includes forward-looking statements concerning a transaction between GBT-Grupo Biotoscana and Pierre Fabre, including expectations regarding the applicability of predictions to the commercialization of certain products. GBT-Grupo Biotoscana disclaims any obligation to update any forward-looking statement, except as required by applicable law.


2 In the United States, Cresemba is approved to treat patients 18 years of age and older for invasive aspergillosis and invasive mucormycosis (Cresemba US prescribing information, accessed September 27, 2018).

3 In Switzerland, isavuconazole is approved for the treatment of adult patients with invasive aspergillosis and for the treatment of mucormycosis in adult patients who are resistant to or intolerant of amphotericin B and in adult patients with moderate to severe renal impairment (full indication in: Swissmedic - approved information for healthcare professionals as of August 2017).