Glossary of terms

ACR

American College of Rheumatology

ACR20 (ACR 20/50/70)

American College of Rheumatology 20% response rate signifies a 20% or greater improvement in the number of swollen and tender joints as well as a 20% or greater improvement in three out of five other disease-activity measures. ACR 50 and ACR70 reflect the same, for 50% and 70% response rates, respectively

ADR

American Depositary Receipt; Galapagos has a Level 3 ADR listed on NASDAQ with ticker symbol GLPG and CUSIP number 36315X101. One ADR is equivalent to one ordinary share in Galapagos NV

Atherogenic index

Total cholesterol over HDL ratio. Improvement of the atherogenic index may be a forecast of cardiovascular health

Attrition rate

The historical success rate for drug discovery and development, based on publicly known development paths. Statistically seen, investment in at least 12 target-based programs is required to ensure that at least one of these will reach a Phase 3 study. Most new drug R&D programs are discontinued before reaching Phase 3 because they are not successful enough to be approved

BID dosing

Twice daily dosing (*bis in die*)

Bioavailability

Assessment of the amount of (candidate) drug that reaches a body's systemic circulation after (oral) administration

Biomarker

Substance used as an indicator of a biological process, particularly to determine whether a candidate drug has a (desired) biological effect

Black & Scholes model

A mathematical description of financial markets and derivative investment instruments that is widely used in the pricing of European options and warrants

Candidate drug

Substance that has satisfied the requirements of early pre-clinical testing and has been selected for development, starting with formal preclinical safety evaluation followed by clinical testing for the treatment of a certain disorder in humans

CFTR

Cystic **F**ibrosis **T**ransmembrane conductance **R**egulator protein. CFTR is an ion channel that transports chloride and thiocyanate ions across epithelial cell membranes. Mutations in the CFTR gene, that codes for the CFTR protein, cause cystic fibrosis

CIR

Crédit d'Impôt Recherche, or research credit. Under the CIR, the French government refunds up to 30% of the annual investment in French R&D operations, over a period of three years. Galapagos benefits from the CIR through its operations in Romainville, just outside Paris

Class II mutation

A genetic mutation in cystic fibrosis resulting in errors in CFTR folding, transport of functional CFTR to the cell membrane, and CFTR channel opening, whereby chloride ion flow at the cell surface in the membrane of affected organs is impacted negatively. More than 90% of cystic fibrosis patients are carriers of the Class II mutation. It is believed that a potentiator and multiple correctors will be needed to address the CFTR malfunction of Class II mutation patients.

Class III mutation

A genetic mutation in cystic fibrosis resulting in errors in CFTR channel opening, whereby chloride ion flow at the cell surface in the membrane of affected organs is impacted negatively. Approximately 4% of cystic fibrosis patients are carriers of the Class III mutation. It is believed that a potentiator is needed to address the malfunction of Class III mutation patients.

Clinical Proof of Concept (PoC)

Point in the drug development process where the candidate drug shows efficacy in a therapeutic setting

Compound

A chemical substance, often a small molecule with drug-like properties

Contract research organization

Organization which provides drug discovery and development services

Corrector drug

Drug that restores the correct protein formation in cystic fibrosis patients. In most CF patients, a potentiator and corrector drug are needed in combination to restore the channel function of the CFTR. Galapagos and AbbVie are planning to combine a potentiator with two correctors to treat CF patients with the most prevalent mutation of CFTR

Crohn's disease (CD)

An inflammatory bowel disease involving inflammation of the small and large intestines, leading to pain, bleeding, and ultimately in some cases surgical removal of parts of the bowel

CRP

C-reactive protein is a protein found in the blood, the levels of which rise in response to inflammation

Cystic fibrosis (CF)

A life-threatening genetic disease that affects approximately 80,000 people worldwide. Although the disease affects the entire body, difficulty breathing is the most serious symptom as a result of clogging of the airways due to mucus build-up and frequent lung infections

DAS28

DAS28 is an RA Disease Activity Score based on a calculation that uses tender and swollen joint counts of 28 defined joints, the physician's global health assessment and a serum marker for inflammation, such as C-reactive protein

Development

All activities required to bring a new drug to the market. This includes pre-clinical and clinical development research, chemical and pharmaceutical development and regulatory filings of drug candidates

Discovery

Process by which new medicines are discovered and/or designed. At Galapagos, this is the department that oversees target and drug discovery research through to nomination of pre-clinical candidates

Disease-modifying

Addresses the cause of disease and modifying the disease progression, not just the symptoms of the disease

Dose-range finding study

Phase 2 clinical study exploring the trade-offs between efficacy and safety among various doses of treatment in patients. Results are used to determine doses for later studies

Drug development

See: Development

Drug discovery

See: Discovery

Efficacy

Effectiveness for intended use

EMA

European Medicines Agency, in charge of European market authorization of new medication

FDA

The U.S. Food and Drug Administration is an agency responsible for protecting and promoting public health and in charge of American market authorization of new medication

Fee-for-service

Payment system where the service provider is paid a specific amount for each procedure or service performed

FIH

First-in-human clinical trial, usually conducted in healthy volunteers with the aim to assess the safety, tolerability and pharmacokinetics of the candidate drug

Filgotinib

Formerly known as GLPG0634. Small molecule selective JAK1 inhibitor which showed excellent efficacy and safety in rheumatoid arthritis and Crohn's disease patients in Phase 2 trials. Filgotinib is partnered with Gilead. Galapagos and Gilead expect to start Phase 3 trials with filgotinib in RA and Crohn's disease in the course of 2016

FSMA

The Belgian market authority: Financial Services and Markets Authority, or *Autoriteit voor Financiële Diensten en Markten*

FTE

Full-time equivalent; a way to measure a worker's involvement in a project. For example, an FTE of 1.0 means that the equivalent work of one full-time worker was used on the project

GLPG0634

Molecule number nowadays known as filgotinib

GLPG1205

Novel mode-of-action medicine, fully owned by Galapagos. GLPG1205 did not meet the primary endpoint in a Phase 2 proof-of-concept study in ulcerative colitis in 2016. Galapagos is exploring other possible indications for GLPG1205

GLPG1690

A novel drug targeting autotaxin, with potential applications in idiopathic pulmonary fibrosis. Fully proprietary to Galapagos. A Phase 2 proof-of-concept study in IPF has been initiated

GLPG1837

A potentiator drug currently in Phase 2 in Class III cystic fibrosis mutation patients

GLPG1972

A novel mode-of-action drug that is part of the osteoarthritis alliance with Servier. GLPG1972 entered Phase 1 in November 2015

GLPG2222

A corrector drug currently in Phase 1

IBD

Inflammatory Bowel Disease. This is a general term for an autoimmune disease affecting the bowel, including Crohn's disease and ulcerative colitis. Crohn's disease affects the small and large intestine, while ulcerative colitis affects the large intestine. Both diseases involve inflammation of the intestinal wall, leading to pain, bleeding, and ultimately in some cases surgical removal of part of the bowel

IPF

Idiopathic pulmonary fibrosis. A chronic and ultimately fatal disease characterized by a progressive decline in lung function. Pulmonary fibrosis involves scarring of lung tissue and is the cause of shortness of breath. Fibrosis is usually associated with a poor prognosis. The term "idiopathic" is used because the cause of pulmonary fibrosis is still unknown

Inflammatory diseases

A large, unrelated group of disorders associated with abnormalities in inflammation

In-/out-licensing

Receiving/granting permission from/to another company or institution to use a brand name, patent, or other proprietary right, in exchange for a fee and/or royalty

Intellectual property

Creations of the mind that have commercial value and are protected by patents, trademarks or copyrights

Intersegment

Occurring between the different operations of a company

Investigational New Drug (IND) application

United States Federal law requires a pharmaceutical company to obtain an exemption to ship an experimental drug across state lines, usually to clinical investigators, before a marketing application for the drug has been approved. The IND is the means by which the sponsor technically obtains this exemption, allowing them to perform clinical studies

JAK

Janus kinases (JAK) are critical components of signaling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in rheumatoid arthritis

Milestone

Major achievement in a project or program; in Galapagos' alliances, this is usually associated with a payment

MTX

Methotrexate

Molecule collections

Chemical libraries, usually consisting of drug-like small molecules that are designed to interact with to specific target classes. These collections can be screened against a target to generate initial "hits" in a drug discovery program

MOR106

A novel mode-of-action antibody that is being developed in inflammatory diseases and part of the alliance with MorphoSys. MOR106 has entered Phase 1 in Q1 2016

NDA

New Drug Application

Oral dosing

Administration of medicine by the mouth, either as a solution or solid (capsule, pill) form

Osteoarthritis

The most common form of arthritis, usually occurring after middle age, marked by chronic breakdown of cartilage in the joints leading to pain, stiffness, and swelling

Outsourcing

Contracting work to a third party

Pharmacokinetics (PK)

Study of what a body does to a drug; the fate of a substance delivered to a body. This includes absorption, distribution to the tissues, metabolism and excretion. These processes determine the blood concentration of the drug and its metabolite(s) as a function of time from dosing

Phase 1

First stage of clinical testing of a potential new treatment designed to assess the safety and tolerability, pharmacokinetics of a drug, usually performed in a small number of healthy human volunteers

Phase 2

Second stage of clinical testing, usually performed in 20-300 patients, in order to determine efficacy, tolerability and the most effective dose to use

Phase 3

Large clinical trials, usually conducted in 300-3000 patients to gain a definitive understanding of the efficacy and tolerability of the candidate treatment by comparing it to the "gold standard" treatment; serves as the principal basis for regulatory approval

Placebo-controlled

A clinical study can only show statistical significance when the effect of a candidate drug is measured against that of a placebo, a substance having no pharmacological effect but administered as a control in testing experimentally or clinically the efficacy of a biologically active preparation

Potentiator drug

Drug that restores the CFTR ion channel opening in cystic fibrosis patients. In most CF patients, a potentiator and corrector drug are needed in combination to restore the genetic defect causing CF. Galapagos and AbbVie are planning to combine a potentiator with two correctors to treat CF patients with the most prevalent mutation of CFTR

Pre-clinical

Stage of drug research development, undertaken prior to the administration of the drug to humans. Consists of *in vitro* and *in vivo* screening, pharmacokinetics, toxicology, and chemical upscaling

Pre-clinical candidate (PCC)

A new molecule and potential drug that meets chemical and biological criteria to begin the development process

Rheumatoid arthritis (RA)

A chronic, systemic inflammatory disease that causes joint inflammation, and usually leads to cartilage destruction, bone erosion and disability

R&D operations

Research and development operations; unit responsible for discovery and developing new candidate drugs for internal pipeline or as part of risk/reward sharing alliances with partners

Screening

Method usually applied at the beginning of a drug discovery campaign, where a target is tested in a biochemical assay against a series of small molecules or antibodies to obtain an initial set of "hits" that show activity against the target. These hits are then further tested or optimized

Service operations

Business unit primarily focused on delivering products and conducting fee-for-service work for clients. Galapagos' service operations included the BioFocus and Argenta business units, which were both sold in April 2014 to Charles River Laboratories

Target

Protein that has been shown to be involved in a disease process and forms the basis of therapeutic intervention or drug discovery

Target discovery

Identification and validation of proteins that have been shown to play a role in a disease process

Technology access fee

License payment made in return for access to specific technology (e.g. compound or virus collections)

TNF

Tumor necrosis factor

Ulcerative colitis (UC)

UC is an inflammatory bowel disease (IBD) causing chronic inflammation of the lining of the colon and rectum (unlike CD with inflammation throughout the gastrointestinal tract)

Financial calendar

29 July 2016

First Half 2016 Results

28 October 2016

Third Quarter 2016 Results

3 March 2017

Full Year 2016 Results

Financial year
The financial year starts on 1 January and ends on 31 December.

Auditor
Deloitte Bedrijfsrevisoren B.V. o.v.v.e. CVBA, represented by Gert Vanhees
Berkenlaan 8b
1831 Diegem, Belgium

Colophon

Concept, design, and online programming
nexxar GmbH, Vienna - Online annual reports and online sustainability reports
www.nexxar.com

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Felix Kalkman

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Contact

Elizabeth Goodwin
Vice President Investor Relations & Corporate Communications
Galapagos NV
Generaal De Wittelaan L11 A3
2800 Mechelen, Belgium
Tel. +32 15 34 29 00
Mob. +1 781 460 1784
Email: ir@glpg.com