

Glossary of terms

100 points clinical response

Percentage of patients achieving a 100 point decrease in CDAI score during a clinical trial in Crohn's disease patients

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. ACR50 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

AFM

Dutch Authority for the Financial Markets

Anemia

Condition in which there are an inadequate number of red blood cells to carry oxygen to the body's tissues

(anti-)TNF

Tumor necrosis factor. An anti-TNF drug acts by modulation of TNF

Atherogenic index

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

Atopic dermatitis (AtD)

Also known as atopic eczema, atopic dermatitis is a common pruritis inflammatory condition affecting the skin, which most frequently starts in childhood

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

Autotaxin (ATX)

An enzyme important for generating the signalling molecule lypophosphatidic acid (LPA). GLPG1690 targets autotaxin for IPF

BID dosing

Twice daily dosing (bis in die)

Bioavailability

Assessment of the amount of product candidate 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 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

Bleomycin mouse model

A pre-clinical model involving use of bleomycin (a cancer medication) to induce IPF symptoms

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

CDAI

Crohn's Disease Activity Index, evaluating patients on 8 different factors, each of which has a pre-defined weight as a way to quantify the impact of Crohn's disease

CFTR

Cystic Fibrosis Transmembrane conductance Regulator 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. Orkambi is the only approved disease-modifying therapy for Class II mutation patients today

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. Kalydeco is the only approved disease-modifying therapy for Class III mutation patients today

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 investigate in 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

Cytokine

A category of small proteins which play important roles in signaling in processes in the body

DARWIN

Phase 2 program for filgotinib in rheumatoid arthritis: completed and reported in 2015 (except for the currently still ongoing DARWIN 3 study). DARWIN 1 explored three doses, in bid and qd administration, for up to 24 weeks in RA patients with insufficient response to methotrexate (MTX) and who remained on their stable background treatment with MTX. DARWIN 2 explored three qd doses for up to 24 weeks in RA patients with insufficient response to methotrexate (MTX) and who washed out of their treatment with MTX. DARWIN 1 and 2 were double-blind, placebo-controlled trials which recruited approximately 900 patients globally. DARWIN 3 is a long term extension trial currently ongoing; all patients are on 200 mg filgotinib, except for U.S. males who are on 100 mg.

DAS28 (CRP)

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. DAS28(CRP) includes c-reactive protein the score calculation: scores range from 2.0 to 10.0, with scores below 2.6 being considered remission.

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

DIVERSITY

Phase 3 program evaluating filgotinib in Crohn's disease

Dose-range finding study

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

Double-blind

Term to characterize a clinical trial in which neither the physician nor the patient knows if the patient is taking placebo or the treatment being evaluated

Efficacy

Effectiveness for intended use

EMA

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

Endoscopy

A non-surgical procedure involving use of an endoscope to examine a person's digestive tract

Esbriet

An approved drug (pirfenidone) for IPF, marketed by Roche

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

Fibrotic score

The Ashcroft fibrotic score involves measuring pulmonary fibrosis through examination of histopathology tissue

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 promising safety and activity profile in RA and Crohn's disease patients in Phase 2 trials. Filgotinib is partnered with Gilead. Galapagos and Gilead are running Phase 3 trials with filgotinib in RA, CD and UC. Gilead initiated Phase 2 studies with filgotinib in small bowel Crohn's disease, fistulizing Crohn's disease, and Sjögren's syndrome; Galapagos initiated Phase 2 studies with filgotinib in ankylosing spondylitis and psoriatic arthritis. We expect to initiate more Phase 2 trials with filgotinib in new indications in the course of 2017. Filgotinib is an investigational drug and its efficacy and safety have not been established.

FINCH

Phase 3 program evaluating filgotinib in RA

Fistulizing Crohn's disease

Fistulae are inflammatory tracts that most often occur between the distal colon and the perianal region. Fistulae are one of the most severe sequelae of luminal CD and the lifetime risk of occurrence is close to 50% of those with active CD.

FITZROY

A double-blind, placebo controlled Phase 2 trial with filgotinib in 177 CD patients for up to 20 weeks; full results were published in The Lancet in 2016

FLORA

A double-blind, placebo-controlled exploratory Phase 2a trial with GLPG1690 in up to 24 IPF patients; topline results are expected in H₂ 2017

FSMA

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

FTE

Fulltime 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 currently known as filgotinib

GLPG1690

A novel product candidate targeting autotaxin, with potential application in idiopathic pulmonary fibrosis. Fully proprietary to Galapagos. Testing in Phase 2 proof-of-concept FLORA study in IPF underway, with topline results expected in H₂ 2017

GLPG1837

A potentiator product candidate which showed activity and favorable safety in the SAPHIRA 1 and 2 trials in Phase 2 in Class III CF mutation patients

GLPG1972

A novel mode-of-action product candidate that is part of the OA alliance with Servier. GLPG1972 was well-tolerated and showed no emerging safety signals in a Phase 1 trial with healthy volunteers. In addition, GLPG1972 showed up to 60% reduction in a relevant OA biomarker within 14 days in these volunteers. Galapagos expects to initiate a Phase 1b trial with GLPG1972 in OA patients in the U.S. in 2017

GLPG2222

A C1 (early) corrector product candidate which showed favorable safety in Phase 1 and is currently being tested in the ALBATROSS Phase 2 study in combination with Kalydeco in Class III mutation patients. In February 2017 Galapagos announced first dosing of GLPG2222 with GLPG2451 in healthy volunteers

GLPG2451

A potentiator product candidate currently undergoing a Phase 1 safety trial. In February 2017 Galapagos announced first dosing of GLPG2222 with GLPG2451 in healthy volunteers

GLPG2534

A pre-clinical candidate with novel mode of action with potential application in AtD. GLPG2543 is expected to enter Phase 1 trials in 2017

GLPG2737

A C2 (late) corrector product candidate currently in a Phase 1 safety trial

GLPG2851

A C1 (early) corrector product candidate currently at the pre-clinical stage. GLPG2851 is expected to enter Phase 1 trials in 2017

GLPG2938

A pre-clinical candidate with novel mode of action with potential application in IPF. GLPG2938 is expected to enter Phase 1 trials in 2017

GLPG3067

A potentiator drug candidate. GLPG3067 started a Phase 1 trial in March 2017

GLPG3221

A C2 (late) corrector drug candidate currently at the pre-clinical stage. GLPG3221 is expected to enter Phase 1 trials in 2017

HDL

High-density lipoprotein. HDL scavenges and reduces low-density lipoprotein (LDL) which contributes to heart disease at high levels. High levels of HDL reduce the risk for heart disease, while low levels of HDL increase the risk of heart disease*

* Source: webmd.com/cholesterol-management/guide/hdl-cholesterol-the-good-cholesterol#1

Hemoglobin

A protein inside red blood cells that carries oxygen from the lungs to tissues and organs in the body and carries carbon dioxide back to the lungs

Heterozygous

Genetic term meaning a cell containing different alleles for a gene

Histopathology

Microscopic examination of tissues for manifestations of a disease

Homozygous

Genetic term meaning identical alleles of the gene are present on both homologous chromosomes

IBD

Inflammatory Bowel Disease. This is a general term for an autoimmune disease affecting the bowel, including CD and UC. CD affects the small and large intestine, while UC 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

IL-17C

IL-17C has been shown to be distinct from other members of the IL-17 family of cytokines. IL-17C has been shown to be an important mediator in inflammatory skin diseases, and is the target of MOR106

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

In vitro

Studies performed with cells outside their natural context, for example in a laboratory

Inflammatory diseases

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

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 obtains this exemption, allowing them to perform clinical studies

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

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. Filgotinib is a selective JAK1 inhibitor

Kalydeco

A potentiator drug marketed by Vertex Pharmaceuticals

LDL

Low-density lipoprotein. LDL contributes to heart disease at high levels*

* Source: webmd.com/cholesterol-management/guide/hdl-cholesterol-the-good-cholesterol#1

Liver enzymes

Inflamed or injured liver cells secrete higher than normal amounts of certain chemicals, including liver enzymes, into the bloodstream*

* Source: Mayoclinic.org

LPA

Lysophosphatidic acid, or LPA, is a signaling molecule involved in fibrosis

Lymphocyte

Type of white blood cell that is part of the immune system

Milestone

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

Molecule collections

Chemical libraries, usually consisting of drug-like small molecules that are designed to interact with 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 product candidate currently being evaluated in AtD patients in a Phase 1b trial. MOR106 acts on IL-17C, a novel antibody target discovered by Galapagos. MOR106 is part of the alliance with MorphoSys

MTX

Methotrexate; a first-line therapy for inflammatory diseases

NDA

New Drug Application

Neutrophil

Type of immune system cell which is one of the first cell types to travel to the site of an infection in the body. Neutrophils are another type of white blood cell which fight infection by ingesting and killing microorganisms

NK cells

Natural killer cells, type of white blood cell with granules of enzymes which can attack tumors or viruses

Ofev

An approved drug (nintedanib) for IPF, marketed by Boehringer Ingelheim

Oral dosing

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

Organoids

Miniature organ produced from cells from a donor; organoids have all the phenotypic characteristics of the patient donor, making them useful tools for *in vitro* drug research

Orkambi

A combination potentiator-corrector therapy marketed by Vertex Pharmaceuticals

Osteoarthritis (OA)

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 an investigational drug 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 no more than several hundred patients, in order to determine efficacy, tolerability and the dose to use

Phase 3

Large clinical trials, usually conducted in several hundred to several thousand patients to gain a definitive understanding of the efficacy and tolerability of the candidate treatment; serves as the principal basis for regulatory approval

Placebo-controlled

A substance having no pharmacological effect but administered as a control in testing of a biologically active preparation

Potentiator drug

Drug that restores the CFTR ion channel opening in CF 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 investigate 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

Proof of Concept study

Phase 2 patient study in which activity as well as safety in patients is evaluated, usually for a new mechanism of action

Pruritis

Extreme itching, as observed in AtD patients

QD dosing

Once daily dosing (quaque die)

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

Rheumatoid arthritis (RA)

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

SAPHIRA

A Phase 2 trial of potentiator GLPG1837 in cystic fibrosis patients carrying a Class III mutation. Results were reported in 2016, showing activity and favorable safety in two Class III mutations

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

SELECTION

Phase 2/3 program evaluating filgotinib in UC patients. Galapagos expects an interim readout for the Phase 2 portion of the program in late 2017

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

SES-CD scores

Simple Endoscopic Score for Crohn's Disease, involving review of 5 pre-defined bowel segments, assigning values from 0 (unaffected) to 3 (highly affected)

Small bowel CD

Crohn's disease causes chronic inflammation and erosion of the intestines. It can affect different regions of GI tract including the stomach and small and large intestines. While isolated SBCD is an uncommon presentation of CD, involvement of some portion of the small bowel (SB), particularly the ileum, is common

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)

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

27 July 2017

First Half 2017 Results

26 October 2017

Third Quarter 2017 Results

22 February 2018

Full Year 2017 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
Luchthaven Nationaal 1, bus J, 1930
Zaventem, Belgium

Colophon

Concept, design, and online programming

nexxar GmbH, Vienna - Online annual reports
and online sustainability reports

www.nexxar.com

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