



Glossary of terms

Glossary of terms, to be read only in conjunction with this Q1 Report 2018.

100 points clinical response

Percentage of patients achieving a 100-point decrease in CDAI score during a clinical trial in CD 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

ADAMTS-5

ADAMTS-5 is a key enzyme involved in cartilage breakdown (Larkin 2015)

ADS

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

AFM

Dutch Authority for the Financial Markets

ALBATROSS

A Phase 2 trial to evaluate GLPG2222 in ivacaftor-treated CF patients with the Class II mutation on one allele

Anemia

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

Ankylosing spondylitis (AS)

AS is a systemic, chronic, and progressive spondyloarthropathy primarily affecting the spine and sacroiliac joints, and progressing into severe inflammation that fuses the spine, leading to permanent painful stiffness of the back

(anti-)TNF

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

ASDAS

Ankylosing Spondylitis Disease Activity Score, a composite score of symptoms such as back pain, duration of morning stiffness, and peripheral pain and swelling. We measure ASDAS scores in the TORTUGA trial with filgotinib in AS



OTHER INFORMATION

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 signaling 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 product candidate 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 model

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

CDAI

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

CDAI remission

In the FITZROY trial, the percentage of patients with CD who showed a reduction of CDAI score to <150

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 CF



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 CF 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. About 90% of CF 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 and Symdeko are the only approved disease-modifying therapies for Class II mutation patients today

Class III mutation

A genetic mutation in CF 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 8% of CF 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 product candidate 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 CF 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 be investigated in CF patients with the most prevalent mutation of CFTR

Crohn's disease (CD)

An IBD 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



OTHER INFORMATION

Cytokine

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

Dactylitis

Dactylitis is inflammation of a digit (either finger or toe) and is derived from the Greek word dactylos meaning finger. The affected fingers and/or toes swell up into a sausage shape and can become painful. Dactylitis will be measured in the EQUATOR trial with filgotinib in psoriatic arthritis

DARWIN

Phase 2 program for filgotinib in RA. Completed and reported in 2015 (except for the currently still ongoing DARWIN 3 study). DARWIN 1 explored three doses, in twice-daily and once-daily 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 once-daily 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 product 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 disease itself, modifying the disease progression, not just the symptoms of the disease

DIVERSITY

Phase 3 program evaluating filgotinib in CD

DLCO

DLCO (diffusion capacity of the lung for carbon monoxide) is the extent to which oxygen passes from the air sacs of the lungs into the blood. This is measured in IPF patients

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



OTHER INFORMATION

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

Enthesitis

Inflammation of the tendons or ligaments; this is one of the key symptoms of psoriatic arthritis

EQUATOR

A Phase 2 trial with filgotinib in psoriatic arthritis patients

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 approval of new medications

Fee-for-service

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

FEV

Forced expiratory volume measures how much air a person can exhale during a forced breath. The amount of air exhaled may be measured during the first (FEV1), second (FEV2), and/or third seconds (FEV3) of the forced breath

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 product candidate

Filgotinib

Formerly known as GLPG0634. Small molecule selective JAK1 inhibitor which showed activity and favorable tolerability in RA and CD 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 and Phase 2 trials with filgotinib in additional indications. Filgotinib is an investigational drug and its efficacy and safety have not been established



OTHER INFORMATION

FINCH

Phase 3 program evaluating filgotinib in RA

Fistulizing CD

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

FLAMINGO

A Phase 2 study to evaluate GLPG2222 in patients with CF with the F508del mutation on both alleles

FLORA

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

FRI

Functional respiratory imaging is a technology which enhances 3D visualization and quantification of a patient's airway and lung geometry

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 an employee'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

FVC

Forced vital capacity is the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible. FVC is used to help determine both the presence and severity of lung diseases such as IPF

GLPG0634

Molecule number currently known as filgotinib

GLPG1205

A GPR84 inhibitor fully proprietary to us. We plan to initiate a patient trial with GLPG1205 in IPF

GLPG1690

A novel drug targeting autotaxin, with potential application in IPF. Fully proprietary to Galapagos. Topline results from the Phase 2a FLORA trial were reported in August 2017

GLPG1837

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



OTHER INFORMATION

GLPG1972

A novel mode-of-action product candidate that is part of the OA alliance with Servier. Galapagos reported positive results in a Phase 1b trial with GLPG1972 in OA patients in the United States in 2017

GLPG2222

A C1 (early) corrector drug candidate which showed favorable tolerability in Phase 1 and activity and favorable tolerability in the ALBATROSS Phase 2 trial in combination with Kalydeco in Class III mutation patients and in the FLAMINGO trial as monotherapy in Class II mutation patients

GLPG2451

A potentiator drug candidate which showed favorable tolerability in Phase 1, also in combination with C1 corrector GLPG2222

GLPG2534

A pre-clinical candidate with a novel mode of action. GLPG2534 is expected to enter Phase 1 trials in 2018

GLPG2737

A C2 (late) corrector drug candidate which showed favorable tolerability in a Phase 1 safety trial. GLPG2737 is currently being tested in the PELICAN trial in combination with Orkambi in Class II mutation CF patients

GLPG2851

A C1 (early) corrector drug candidate which entered Phase 1 trials in 2017

GLPG3067

A potentiator drug candidate which showed favorable tolerability in a Phase 1 trial in 2017, in combination with GLPG2222

GLPG3121

A pre-clinical candidate with undisclosed novel mode of action directed toward inflammation

GLPG3221

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

GLPG3312

A pre-clinical candidate with undisclosed mode of action directed toward inflammation

GLPG3499

A pre-clinical candidate with undisclosed mode of action in the IPF program

GLPG3535

A pre-clinical candidate with undisclosed mode of action directed toward pain in the alliance with Calchan

GLPG3667

A pre-clinical candidate with novel mode of action directed toward inflammation



OTHER INFORMATION

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

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

Inspiratory capacity

Total lung capacity or the amount of gas contained in the lung at the end of a maximal inhalation

Intellectual property

Creations of the mind that have commercial value and are protected or protectable, including 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

ISABELA

Phase 3 clinical program investigating GLPG1690 in IPF patients

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 RA. Filgotinib is a selective JAK1 inhibitor

Kalydeco

A potentiator drug (ivacaftor) marketed by Vertex Pharmaceuticals

LDL

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

Liver enzymes

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

LPA

Lysophosphatidic acid (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 our 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 which completed a Phase 1b trial in AtD patients. MOR106 acts on IL-17C, a novel antibody target discovered by Galapagos. MOR106 is part of the alliance with MorphoSys



OTHER INFORMATION

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

PELICAN

Phase 2 trial of C2 corrector GLPG2737 in combination with Orkambi in Class II mutation CF patients

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



OTHER INFORMATION

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 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 in 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

Product candidate

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

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

Psoriatic arthritis

Psoriatic arthritis is an inflammatory form of arthritis, affecting up to 30% of psoriasis patients. Psoriatic arthritis can cause swelling, stiffness and pain in and around the joints, and cause nail changes and overall fatigue

QD dosing

Once-daily dosing (qd from the Latin quaque die)



OTHER INFORMATION

R&D operations

Research and development operations; unit responsible for discovery and developing new product candidates 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 CF patients carrying a Class III mutation

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

Service operations

Business unit primarily focused on delivering products and conducting fee-for-service work for clients. Our 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 CD, involving review of five pre-defined bowel segments, assigning values from 0 (unaffected) to 3 (highly affected)

Sjögren's syndrome

Sjögren's Syndrome is a systemic inflammatory disease which can be felt throughout the body, often resulting in chronic dryness of the eyes and mouth

Small bowel CD (SBCD)

CD causes chronic inflammation and erosion of the intestines. It can affect different regions of gastrointestinal 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, particularly the ileum, is common

Spondylitis

About 20% of patients with psoriatic arthritis will develop spinal involvement, which is called psoriatic spondylitis. Inflammation of the spine can lead to complete fusion, as in AS, or affect only certain areas such as the lower back or neck. We measure spondylitis in the EQUATOR trial with filgotinib in psoriatic arthritis

Sweat chloride

The sweat test measures the concentration of chloride that is excreted in sweat. It is used to screen for CF. Due to defective chloride channels (CFTR), the concentration of chloride in sweat is elevated in individuals with CF



OTHER INFORMATION

Symdeko

A corrector-potentiator combination for CF patients with the Class II mutation; marketed by Vertex Pharmaceuticals

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)

Tendinitis

Tendinitis is inflammation or irritation of a tendon, the thick fibrous cords that attach muscle to bone. The condition causes pain and tenderness just outside a joint. We measure tendinitis in the EQUATOR trial with filgotinib in psoriatic arthritis

Tezacaftor

C1 corrector for CF therapy developed by Vertex Pharmaceuticals

TORTUGA

Phase 2 trial with filgotinib in patients with ankylosing spondylitis

Ulcerative colitis (UC)

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

Uveitis

Uveitis is the term that refers to inflammation inside the eye. This inflammation can be caused by infection, autoimmune reaction, or by conditions confined primarily to the eye



Financial calendar

2 August 2018 (webcast 3 August)

Half Year 2018 Results

25 October 2018 (webcast 26 October)

Third quarter 2018 Results

21 February 2019 (webcast 22 February)

Full Year 2018 Results

Financial year

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

Auditor

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Colophon

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Visuals in this report are an artist impression,
the purpose is not to represent reality.

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This report is also available in Dutch and
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