

October 27, 2020

Biotechnology

**HOLD**

Price \$127.27

**FLASH NOTE****TOLEDO Program Reveal Not Thesis Changing; Still Very Much A "Show Me" Story****Summary**

We are reiterating our Hold rating on shares after the company hosted its TOLEDO R&D roundtable where they officially disclosed the target and mechanism of action. While we find the target interesting and management seems very optimistic (CEO called it a "once in a lifetime opportunity"), we don't think this changes the sentiment on the stock in the near-to-medium term. Given the setback with filgotinib in the US and the recent failure of GLPG1972 in knee osteoarthritis, we don't think investors are in a rush to assign more value for GLPG's R&D engine/pipeline, particularly when management is setting the bar very high for TOLEDO ahead of signal finding study results in 2021-2022. Beyond its pipeline, we think upside for shares largely relies on US approval of filgotinib in RA and whether its profile will even be competitive vs. the incumbent JAKs, the latter we aren't very confident in.

**Key Points**

Though the targets of the TOLEDO program are now public — there are still many questions to answer and a lot of derisking to be done. The targets are salt-inducible kinases (SIK1/2/3) that management believes are master regulators of the balance between inflammatory and immunoregulatory functions. The key point that management continues to highlight about the TOLEDO program is that inhibition of these targets seem to generate a balanced effect: down regulation of "pro-inflammatory" functions and upregulation of "immune modulating" functions. This mechanism is unique — nearly all other approved or late-stage anti-inflammatory therapies to-date inhibit pro-inflammatory processes. The CSO highlighted some high-level data demonstrating the breadth of efficacy SIK inhibition. Those results appeared to demonstrate that SIK inhibition is efficacious across numerous inflammatory and fibrotic disease models with a range of etiologies from innate immune overactivity to adaptive immune overactivity and everything in between. In our view, at the extremes there are two ways to interpret these results: first, (and management's view) is that this is a once in a lifetime mechanism of action; second, is that SIK inhibition may be a "jack of all trades, master of none." Remember, corticosteroids are oral therapies with incredible breadth of efficacy and activity but, due to this pleiotropy, come with a litany of side effects. Improving on the profile of corticosteroids (via more selective therapies) has been the primary goal of immunological drug development for decades. We think it is really too early to take a strong position at either end of this spectrum. At this point our concern is what it will ultimately cost for clarity about whether SIK inhibition is clinically differentiated and where it is clinically differentiated; based on the clinical development plan, management is expected to put a lot of human capital and investment behind the program but it's not clear if the company's initial signal finding studies will offer much into TOLEDO's differentiation.

**When will we begin to see data from TOLEDO?** The company plans to employ a similar development strategy as it has with other compounds in its pipeline, which leverages biomarker, initial efficacy and safety data from small signal finding, proof-of-concept studies with the idea to move right into Phase 2 or Phase 3 studies if data are positive. While this is a fair approach and one that has the potential of accelerating development timelines & path to market, while potentially reducing costs, it is also not without risk. We can look to the recent failure of GLPG1972 in knee OA as an example where very early data from a small study did not translate to positive results in a large Ph2. Management offered up its development timelines for TOLEDO as follows: (1) in 2020 - GLPG will initiate five proof-of-concept, signal finding studies. Three of these are already recruiting - the Phase 1 CALOSOMA study (n=25) in psoriasis, the Phase 2 SEA TURTLE study (n=30) in ulcerative colitis (UC), and the Phase 2 LADYBUG study (n=25) in rheumatoid arthritis (RA); (2) in 2021 - GLPG expects top-line data from these first three studies to readout after which, Phase 2b dose-ranging studies will begin in RA, UC, and psoriatic arthritis (PsA) assuming data are positive. The company will also begin proof of concept Phase 2 studies in Sjögren's and systemic lupus erythematosus (SLE) in early 2021; and (3) in 2022 - ideally, the results of the Sjögren's and SLE studies will read out, along with the Phase 2b studies in RA, UC and PsA. After which, they would conduct Phase 3 trials. These could be pretty aggressive timelines and again, we may not see differentiating data for this program until 2022 - thus we are not eager to assign more credit.

Derek C. Archila | (617) 848-2762 | archilad@stifel.com

Bill Grau, PhD | (617) 488-4147 | grauw@stifel.com

Benjamin Porter | (617) 488-4404 | porterb@stifel.com

Jacques Villefranc, PhD | (617) 488-4403 | villefrancj@stifel.com

Stifel Equity Trading Desk | (800) 424-8870

Stifel does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision.

All relevant disclosures and certifications appear on pages 3 - 5 of this report.

**Investment Thesis**

*Our thesis is predicated on: (1) the chance of it receiving a meaningfully differentiated label within the JAK class is low; (2) we are cautious on GILD/GLPG's ability to deliver filgotinib sales ahead of consensus estimates between 2020-2025, which to us seem high; and (3) while we are positive on GLPG's pipeline and its long-term prospects, we don't see any major, near-term catalysts from the pipeline that would sufficiently offset our commercial concerns. While there is a lot to like here, given GLPG's meaningful cash position and robust R&D engine, we would seek a better entry point.*

---

**Target Price Methodology/Risks**

Our target price for GLPG shares is \$138. This is based on a probability-weighted, risk-adjusted NPV analysis. We assign \$34, \$2, \$1, \$5 for filgotinib, GLPG1690, Other revenue, Other pipeline, respectively. We assign \$96 of value for cash.

Risks: Underperforming filgotinib consensus sales, failures from the pipeline, delays from the pipeline, competition.

**Company Description**

Galapagos is a clinical-stage biotechnology company specialized in the discovery and development of disease modifying, small molecule medicines with novel mechanisms of action. The pipeline includes clinical candidates focused on rheumatoid arthritis, inflammatory bowel disease, idiopathic pulmonary fibrosis, osteoarthritis, and atopic dermatitis. Lead assets include filgotinib (partnered with Gilead), GLPG1690 in IPF, and GLPG1972 in OA. Galapagos recently signed a transformational deal with Gilead that brought in significant cash and should allow for accelerated R&D. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 460 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France and Croatia.

## Important Disclosures and Certifications

I, Derek C. Archila, certify that the views expressed in this research report accurately reflect my personal views about the subject securities or issuers; and I, Derek C. Archila, certify that no part of my compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this research report. Our European Policy for Managing Research Conflicts of Interest is available at [www.stifel.com/institutional/ImportantDisclosures](http://www.stifel.com/institutional/ImportantDisclosures)

## Galapagos NV (GLPG) as of October 26, 2020 (in USD)



\*Represents the value(s) that changed.

Buy=B; Hold=H; Sell=S; Discontinued=D; Suspended=SU; Discontinued=D; Initiation=I

For a price chart with our ratings and target price changes for GLPG go to <http://stifel2.bluematrix.com/sellside/Disclosures.action?ticker=GLPG>

Prior to July 10, 2020, a different Stifel research analyst provided research coverage of Galapagos NV and its securities. Galapagos NV's price chart for the period prior to July 10, 2020 reflects the rating and price target history of the former Stifel research analyst for such issuer and its securities.

Stifel or an affiliate expects to receive or intends to seek compensation for investment banking services from Galapagos NV in the next 3 months.

Stifel or an affiliate is a market maker or liquidity provider in the securities of Galapagos NV.

The equity research analyst(s) responsible for the preparation of this report receive(s) compensation based on various factors, including Stifel's overall revenue, which includes investment banking revenue.

Our investment rating system is three tiered, defined as follows:

**BUY** -We expect a total return of greater than 10% over the next 12 months with total return equal to the percentage price change plus dividend yield.

**HOLD** -We expect a total return between -5% and 10% over the next 12 months with total return equal to the percentage price change plus dividend yield.

**SELL** -We expect a total return below -5% over the next 12 months with total return equal to the percentage price change plus dividend yield.

Occasionally, we use the ancillary rating of **SUSPENDED** (SU) to indicate a long-term suspension in rating and/or target price, and/or coverage due to applicable regulations or Stifel policies. Alternatively, **SUSPENDED** may indicate the analyst is unable to determine a "reasonable basis" for rating/target price or estimates due to lack of publicly available information or the inability to quantify the publicly available information provided by the company and it is unknown when the outlook will be clarified. **SUSPENDED** may also be used when an analyst has left the firm.

Of the securities we rate, 52% are rated Buy, 31% are rated Hold, 2% are rated Sell and 15% are rated Suspended.

Within the last 12 months, Stifel or an affiliate has provided investment banking services for 21%, 5%, 5% and 7% of the companies whose shares are rated Buy, Hold, Sell and Suspended, respectively.

Within the last 12 months, Stifel or an affiliate has provided material services for 37%, 17%, 35% and 14% of the companies whose shares are rated Buy, Hold, Sell and Suspended, respectively.

## Additional Disclosures

The enclosed materials include information derived from market research information provided by IQVIA, Inc. and its affiliated companies ("IQVIA"). IQVIA market research information is proprietary to IQVIA and available on a confidential basis by subscription from IQVIA. IQVIA market research information reflects estimates of marketplace activity and should be treated accordingly.

Please visit the Research Page at [www.stifel.com](http://www.stifel.com) for the current research disclosures and respective target price methodology applicable to the companies mentioned in this publication that are within Stifel's coverage universe. For a discussion of risks to target price including basis of valuation or methodology please see our stand-alone company reports and notes for all stocks.

The information contained herein has been prepared from sources believed to be reliable but is not guaranteed by us and is not a complete summary or statement of all available data, nor is it considered an offer to buy or sell any securities referred to herein. Opinions expressed are subject to change without notice and do not take into account the particular investment objectives, financial situation or needs of individual investors. Employees of Stifel, or its affiliates may, at times, release written or oral commentary, technical analysis or trading strategies that differ from the opinions expressed within. Stifel or any of its affiliates may have positions in the securities mentioned and may make purchases or sales of such securities from time to time in the open market or otherwise and may sell to or buy from customers such securities on a principal basis; such transactions may be contrary to recommendations in this report. Past performance should not and cannot be viewed as an indicator of future performance.

As a multi-disciplined financial services firm, Stifel regularly seeks investment banking assignments and compensation from issuers for services including, but not limited to, acting as an underwriter in an offering or financial advisor in a merger or acquisition, or serving as a placement agent in private transactions.

#### Affiliate Disclosures

References to "Stifel" (collectively "Stifel") refer to SFC and other associated affiliated subsidiaries including (i) Stifel, Nicolaus & Company, Incorporated ("SNC"); (ii) Keefe, Bruyette & Woods, Incorporated ("KBWI"), which are both U.S. broker-dealers registered with the United States Securities and Exchange Commission ("SEC") and members of the Financial Industry National Regulatory Authority ("FINRA"), respectively; (iii) Stifel Nicolaus Europe Limited ("SNEL"), which is authorised and regulated by the United Kingdom Financial Conduct Authority ("FCA") (FRN 190412) and is a member of the London Stock Exchange and also trades under the name Keefe, Bruyette & Woods Europe ("KBW Europe"); (iv) our MainFirst affiliates (collectively "MAINFIRST"): MainFirst Bank AG, which is regulated by the German Federal Financial Services Authority (Bundesanstalt für Finanzdienstleistungsaufsicht; "BaFin"), MainFirst Schweiz AG, which is regulated by the Eidgenössische Finanzmarktaufsicht ("FINMA"), and MainFirst Securities US Inc. which is a U.S. broker-dealer registered with the SEC and member of FINRA; and (v) Stifel Nicolaus Canada, Incorporated. ("Stifel Canada"), which is authorised and regulated by Investment Industry Regulatory Organization of Canada ("IIROC"), and also trades under the names "Stifel GMP" and/or "Stifel First Energy".

**Registration of non-US Analysts:** Any non-US research analyst employed by SNEL contributing to this report is not registered/qualified as a research analyst with FINRA and is not an associated person of the US broker-dealer and therefore may not be subject to FINRA Rule 2241 restrictions on communications with a subject company, public appearances, and trading securities held by a research analyst account.

**Global Research Notes:** Stifel Global Research (Cross-Border Research) notes are intended for use only by Institutional or Professional Clients. Research analysts contributing content to these reports are subject to different regulatory requirements based on the jurisdiction in which they operate. Clients seeking additional information should contact the Stifel entity through which they conduct business.

#### MAINFIRST Sponsored research:

At MAINFIRST, analysts may produce issuer paid research ('sponsored research'). This research is produced by analysts in accordance with local regulatory requirements relating to such research. In certain jurisdictions, this issuer paid research may be deemed to be independent research albeit not produced to the same conflicts of interest standards required by all jurisdictions for independent research. Where research has been paid for by an issuer, this will be clearly labelled. Please see our [European Policy for Managing Research Conflicts of Interest](#) for additional information.

#### Country Specific and Jurisdictional Disclosures

**United States:** Research produced and distributed by SNEL is distributed by SNEL to "Major US Institutional Investors" as defined in Rule 15a-6 under the US Securities Exchange Act of 1934, as amended. SNC may also distribute research prepared by SNEL directly to US clients, including US clients that are not Major US Institutional Investors. In these instances, SNC accepts responsibility for the content. SNEL is a non-US broker-dealer and accordingly, any transaction by a US client in the securities discussed in the document must be effected by SNC. US clients wishing to place an order should contact their SNC representative.

**UK and European Economic Area (EEA):** This report is distributed in the EEA by SNEL, which is authorized and regulated in the United Kingdom by the FCA. In these instances, SNEL accepts responsibility for the content. Research produced by SNEL is not intended for use by and should not be made available to non-professional clients.

The complete preceding 12-month recommendations history related to recommendation(s) in this research report is available at <https://stifel2.bluematrix.com/sellside/MAR.action>

**Brunei:** This document has not been delivered to, registered with or approved by the Brunei Darussalam Registrar of Companies, Registrar of International Business Companies, the Brunei Darussalam Ministry of Finance or the Autoriti Monetari Brunei Darussalam. This document and the information contained within will not be registered with any relevant Brunei Authorities under the relevant securities laws of Brunei Darussalam. The interests in the document have not been and will not be offered, transferred, delivered or sold in or from any part of Brunei Darussalam. This document and the information contained within is strictly private and confidential and is being distributed to a limited number of accredited investors, expert investors and institutional investors under the Securities Markets Order, 2013 ("Relevant Persons") upon their request and confirmation that they fully understand that neither the document nor the information contained within have been approved or licensed by or registered with the Brunei Darussalam Registrar of Companies, Registrar of International Business Companies, the Brunei Darussalam Ministry of Finance, the Autoriti Monetari Brunei Darussalam or any other relevant governmental agencies within Brunei Darussalam. This document and the information contained within must not be acted on or relied on by persons who are not Relevant Persons. Any investment or investment activity to which the document or information contained within is only available to, and will be engaged in only with Relevant Persons.

**Canadian Distribution:** Research produced by SNEL is distributed in Canada by SNC in reliance on the international dealer exemption. This material is intended for use only by professional or institutional investors. None of the investments or investment services mentioned or described herein is available to other persons or to anyone in Canada who is not a "permitted client" as defined under applicable Canadian securities law.

**Republic of South Africa:** Research produced by SNEL is distributed by SNEL to "Clients" as defined in FSCA FAIS Notice 20 of 2018 (the "FAIS Notice") issued by the Financial Services Conduct Authority. Research distributed by SNEL is pursuant to an exemption from the licensing requirements under Section 7(1) of the Financial Advisory and Intermediary Services Act, 2002.

In jurisdictions where Stifel is not already licensed or registered to trade securities, transactions will only be affected in accordance with local securities legislation which will vary from jurisdiction to jurisdiction and may require that a transaction is carried out in accordance with applicable exemptions from registration and licensing requirements. Non-US customers wishing to effect transactions should contact a representative of the Stifel entity in their regional jurisdiction except where governing law permits otherwise. US customers wishing to effect transactions should contact their US salesperson.

The recommendation contained in this report was produced at 27 October 2020 15:10EDT and disseminated at 27 October 2020 15:10EDT.

#### **Additional Information Is Available Upon Request**

© 2020 Stifel. This report is produced for the use of Stifel customers and may not be reproduced, re-distributed or passed to any other person or published in whole or in part for any purpose without the prior consent of Stifel. Stifel, Nicolaus & Company, Incorporated, One South Street, Baltimore, MD 21202.