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OUTPERFORM

Reason for report:

FLASH NOTE

Seamus Fernandez
(617) 918-4011
Seamus.Fernandez@Leerink.com

Richard Goss
(617) 918-4059
Richard.Goss@leerink.com

Le-Yi Wang, Ph.D.
(617) 918-4568
Leyi.Wang@leerink.com

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FIBROGEN, INC.

Comparison of HIF-PHI Programs Ahead of GSK's R&D Day

• **Bottom Line:** GSK (MP) is hosting an R&D day tomorrow, during which it plans to provide details on the development program for its hypoxia-inducible factor (HIF)-prolyl hydroxylase inhibitor (PHI) GSK1278862. While GSK has stated that is has a differentiated program from others in development, we believe that it may face several challenges compared to FGEN's roxadustat strategy. At the investor meeting tomorrow, we hope to gain greater clarity on: 1) the details and timing of the Phase III development plan in dialysis-dependent (DD) and non-dialysis-dependent (NDD) chronic kidney disease (CKD), as well as other potential anemia indications; 2) how the company plans to address potential recruitment challenges; 3) the dosing strategy for GSK127886; and 4) how the drug compares to other PHIs in development with respect to the activation of HIF1 vs. HIF2.

• **Roxadustat is well ahead of its competitors in late stage development.** Along with its partners AZN (MP) and Astellas, FGEN is conducting 8 Phase III trials (4 each in DD-CKD and NDD-CKD) across the globe (ex-China), which are anticipated to enroll over 8,000 patients. These trials all started enrollment between 4Q:12 and 4Q:14 and are expected to read-out beginning in 2017. Two additional Phase III studies in China are on track to begin in 4Q:15 and could have data as early as 2H:16. AKBA (NR) plans to initiate trials of its HIF-PHI vadadustat (AKB-6548) in NDD-CKD patients this year and in DD-CKD patients following discussions with regulators. GSK has yet to announce formal plans for GSK1278862, although we hope to learn more at the R&D day tomorrow. BAYRY (NR), Daiichi Sankyo, and Japan Tobacco are all in earlier stages of development with their HIF-PHIs for anemia-related indications.

• **GSK and AKBA could face difficulty enrolling patients.** According to clinicaltrials.gov and estimates from AZN, most of the various Phase III roxadustat trials are expected to take ~2.5-3.5 years to complete. As AKBA and GSK have yet to begin recruitment, it appears that their Phase III trials won't begin to complete until late 2018/early 2019 at the earliest. Additionally, FGEN, AZN, and Astellas have enrolled ~500 clinical trial sites each around the globe (according to FGEN mgmt.), which could make competition for recruitment difficult for AKBA, GSK, and eventually BAYRY once they initiate their studies. GSK has stated their program will be differentiated, but has yet to provide any details on how this might accelerate their development plan.

• **Roxadustat's thrice-weekly (TIW) dosing could prove to be a key differentiator for FGEN.** All of FGEN's Phase III trials (both DD-CKD and NDD-CKD) dose roxadustat TIW. To date, all reported data from its competitors has been from a once-daily (QD) dose of their respective HIF-PHIs (with the exception of one arm from a Phase II DD-CKD trial of vadadustat that tested TIW dosing). FGEN has noted that the frequency of adverse events is related to the time between cycles of therapy and that continuous activation of HIF with QD dosing could increase the risk of safety concerns. AKBA has suggested that it would explore both QD and TIW dosing in its Phase III trials for DD-CKD to obtain more flexibility (TIW dosing coincides with most patients' dialysis schedules), however

Key Stats:	**(NASDAQ :FGEN)**
Sector:	**Biotechnology**
S&P 600 Health Care Index:	**1,652.05**
Price :	**$24.89**
52 Week High:	$40.59
52 Week Low:	$16.95
Shares Outstanding (mil):	59.9
Market Capitalization (mil):	1,490.9

its NDD-CKD registrational program appears to only be investigating QD dosing.

• **Each PHI appears to have different effects on HIF1 vs. HIF2,** with roxadustat preferentially stabilizing HIF1 and vadadustat being more specific for HIF2. While the clinical implications of this difference are unclear, there is some preclinical data to suggesting that HIF1 may act as a kidney cancer tumor suppressor while HIF2 may be a kidney cancer oncoprotein (see our FGEN initiation [LINK] for a more detailed discussion of the safety concerns surrounding prolyl hydroxylase inhibition). We caution that any differences in safety and efficacy based on which HIF is being preferentially activated remain largely theoretical, but nevertheless present a potential point of differentiation between the agents in development. We await further details on GSK1278862's properties.

Disclosures Appendix

Analyst Certification

I, Seamus Fernandez, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

Our valuation for FGEN is $52 a share based on DCF and sum of the parts analysis. We include probability-weighted roxadustat royalties from Astellas (EU and Japan) and AZN (US and ROW) and the 50% roxadustat profit-share with AZN (MP) in China. For all territories, we assume a 70% probability of success for the dialysis-dependent chronic kidney disease (CKD) indication and a 60% probability of success for the non-dialysis dependent CKD indication. We assume a 10% discount rate, which believe is appropriate as given our probability-weighted sales. We currently assign $300M valuation to FGEN's pipeline programs beyond roxadustat.

Risks to Valuation

· Clinical risks including ability for roxadustat to show a statistically significant improvement or clinically relevant trend towards improvement in cardiovascular (CV) outcomes versus erythropoetin-stimulating agents (ESAs) in its Phase III dialysis trials or placebo in its Phase III non-dialysis trials.

· Unknown safety issues associated with PHD inhibition or HIF stabilization.

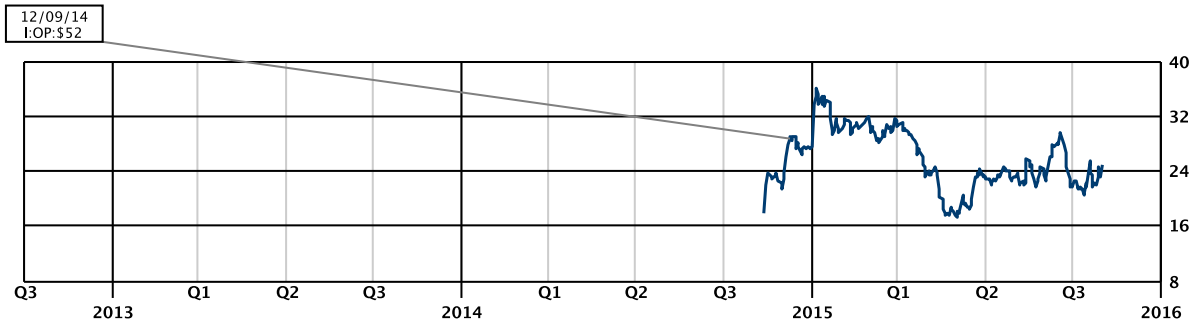
· Clinical and regulatory risks associated with bringing a new class to the market in various territories, particularly in China.

· Uncertain size of the potential anemia market, particularly outside the dialysis setting.

· Unknown reimbursement landscape in the US regarding the inclusion of roxadustat in CMS's Prospective Payment System (aka, "The Bundle").

· Competition from other HIF-PH inhibitors

Rating and Price Target History for: FibroGen, Inc. (FGEN) as of 11-02-2015



OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

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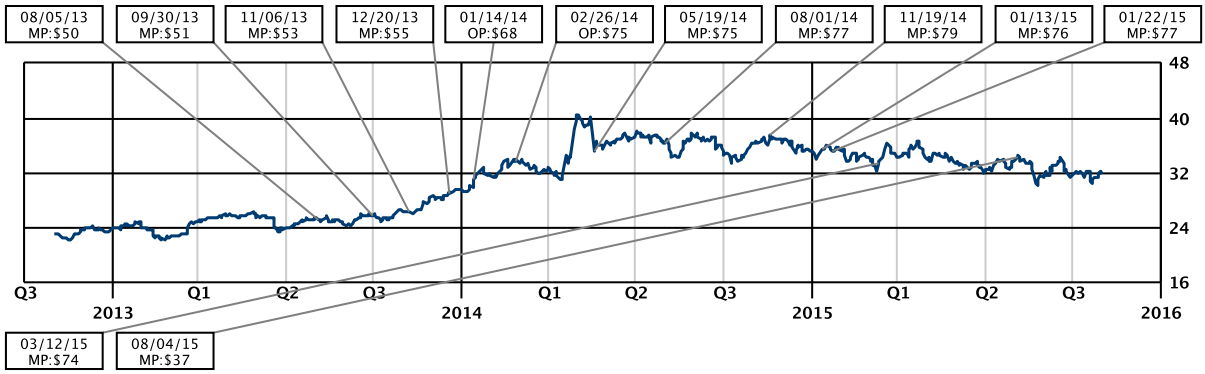
Rating and Price Target History for: AstraZeneca PLC (AZN) as of 11-02-2015



Leerink Swann initiated coverage of AZN with a Market Perform rating on Sept. 30, 2009. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

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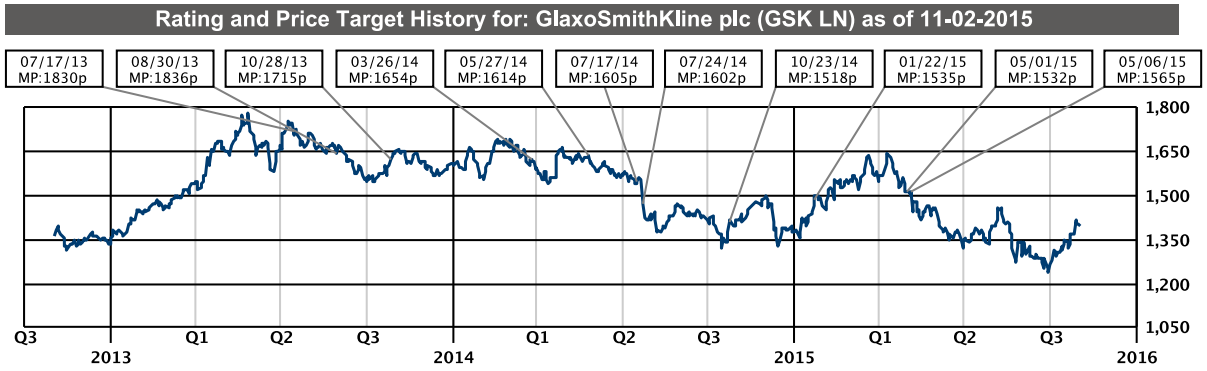

Rating and Price Target History for: GlaxoSmithKline plc (GSK LN) as of 11-02-2015

Leerink Swann initiated coverage of GSK LN with a Market Perform rating on Nov. 24, 2009. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

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Distribution of Ratings/Investment Banking Services (IB) as of 09/30/15				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	167	75.60	68	40.70
HOLD [MP]	54	24.40	2	3.70
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

Important Disclosures

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MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.

In the past 12 months, the Firm has received compensation for providing investment banking services to FibroGen, Inc. .

Leerink Partners LLC makes a market in FibroGen, Inc.

Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of AstraZeneca PLC and GlaxoSmithKline plc on a principal basis.

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Leerink Partners LLC has acted as the manager for a public offering of FibroGen, Inc. in the past 12 months.

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Leerink Partners LLC Equity Research

Director of Equity Research	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	**Alice C. Avanian, CFA**	(617) 918-4544	alice.avanian@leerink.com
Associate Director of Research	**James Kelly**	(212) 277-6096	jim.kelly@leerink.com
Biotechnology	**Seamus Fernandez**	(617) 918-4011	seamus.fernandez@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com
	Richard Goss	(617) 918-4059	richard.goss@leerink.com
	Dae Gon Ha, Ph.D.	(617) 918-4093	daegon.ha@leerink.com
	Mayank Mamtani, MSc.	(617) 918-4887	mayank.mamtani@leerink.com
Major Pharmaceuticals	**Seamus Fernandez**	(617) 918-4011	seamus.fernandez@leerink.com
	Le-Yi Wang, Ph.D.	(617) 918-4568	leyi.wang@leerink.com
Specialty Pharmaceuticals	**Jason M. Gerberry, JD**	(617) 918-4549	jason.gerberry@leerink.com
	Derek C. Archila	(617) 918-4851	derek.archila@leerink.com
	Etzer Darout, Ph.D	(617) 918-4020	etzer.darout@leerink.com
Life Science Tools	**Dan Leonard**	(212) 277-6116	dan.leonard@leerink.com
& Diagnostics	Kevin C. Chen	(212) 277-6045	kevin.chen@leerink.com
	Michael A. Sarcone, CFA	(212) 277-6013	michael.sarcone@leerink.com
Medical Devices, Cardiology	**Danielle Antalffy**	(212) 277-6044	danielle.antalffy@leerink.com
	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com
& Orthopedics	**Richard Newitter**	(212) 277-6088	richard.newitter@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
Healthcare Services	**Ana Gupte, Ph.D.**	(212) 277-6040	ana.gupte@leerink.com
Healthcare Technology	**David Larsen, CFA**	(617) 918-4502	david.larsen@leerink.com
& Distribution	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Digital Health	**Steven Wardell**	(617) 918-4097	steven.wardell@leerink.com
Sr. Editor/Supervisory Analyst	**Mary Ellen Eagan, CFA**	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Randy Brougher		randy.brougher@leerink.com
	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com

New York
299 Park Avenue, 21st floor
New York, NY 10171
(888) 778-1653

Boston
One Federal Street, 37th Floor
Boston, MA 02110
(800) 808-7525

San Francisco
255 California Street, 12th Floor
San Francisco, CA 94111
(415) 905-7200