Media Update

Rezurock® (belumosudil) patient-reported outcomes correlated with clinical response in chronic graft-versus-host disease

* Results demonstrate strong, but not universal, correlation between organ clinical responses and clinically meaningful improvements in patient-reported outcomes from a pooled analysis of ROCKstar and KD025-208 clinical trials

Paris, April 21, 2022. Results from a pooled analysis of Rezurock® (belumosudil) for the treatment of chronic graft-versus-host disease (cGVHD) show certain organ clinical responses correlated with clinically meaningful changes in patient-reported outcomes (PROs). Kadmon, a Sanofi Company, will present the results at the 2022 American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR) Tandem Meetings in Salt Lake City, Utah.

> ***Jonathan Ieyoub***
> Head of Sanofi US Rezurock Medical
> *"These Rezurock data reinforce the importance of patient-reported outcome measures by showing their correlation to clinical response. Knowing the impact that chronic graft-versus-host disease has on patients, the results add support for use of patient-reported outcomes to assess responses in clinical care."*

The pooled analysis of the ROCKstar (KD025-213) and KD025-208 studies demonstrates a very strong, but not universal, correlation between organ clinical response measures and clinically meaningful changes in PROs in patients treated with Rezurock. In particular, the clinically meaningful changes in PROs were reported in the skin, mouth, eye, upper GI, lung (clinical lung scale score), and overall measures. These data support use of PROs for response assessment in cGVHD clinical trials and patient care to help capture the patient's perspective on cGVHD disease activity.

About the Pooled Analysis

The pooled analysis of clinical and PRO data included 170 (91.3%) patients enrolled in two Rezurock studies (n=132, KD025-213; n=54, KD025-208) who had baseline PROs, at least one follow-up PRO, and at least one response assessment. The median age was 54.5 years, 98 (58%) were men, the median number of prior treatments was 3, 70% had severe cGVHD, and the median duration of follow-up at the time of data cut-off was 15 months (range, 0.6-44 months).

Organ responses, defined as complete responses (CR) and partial responses (PR), were 35% (48/135) in skin, 68% (84/124) in joints, 57% (56/99) in mouth, 41% (52/128) in eyes, 73% (19/26) in upper GI, 87% (13/15) in lower GI, 23% (14/61) in lungs, and 77% (130/170) overall. For all organs except for joints, oesophagus, and lower GI there was at least one PRO that was statistically correlated at $p<0.05$ with National Institutes of Health (NIH) organ response. NIH clinical lung response, but not the lung response based on FEV1% change, was associated with the lung PRO.

Correlation of NIH organ response (CR+PR) with clinically meaningful patient-reported outcomes (PROs)						
Organ	Response measure	Clinically meaningful change	Patient-reported outcome	Clinically meaningful change	OR, 95% CI, for improvement in PRO predicting NIH response	p-value
Skin	**NIH Skin score [0-3]**	**1 pt**	**LSS skin scale [0-100]**	**11 pts**	**2.16 (1.12-4.16)**	**0.021**
	Sclerotic skin [0-10]	2 pts	LSS skin scale [0-100]	11 pts	1.66 (0.91-3.01)	0.098

	Sclerotic skin [0-10]	**2 pts**	**Skin tightening [0-10]**	**2 pts**	**2.50 (1.28-4.87)**	**0.007**
Joint	P-ROM [4-25]	2 pts	LSS single item joints [0-4]	1 pt	1.49 (0.84-2.66)	0.175
	NIH joint score [0-3]	1 pt	LSS single item joints [0-4]	1 pt	1.26 (0.73-2.20)	0.408
Mouth	**Oral mucositis rating scale**	**2 pts**	**LSS mouth scale [0-100]**	**13 pts**	**6.36 (2.94-13.74)**	**<0.0001**
	Oral mucositis rating scale	**2 pts**	**Mouth sensitivity [0-10]**	**2 pts**	**4.53 (2.25-9.09)**	**<0.0001**
GI	NIH esophagus score [0-3]	1 pt	LSS nutrition scale [0-100]	7 pts	1.32 (0.53-3.29)	0.546
	NIH upper GI score [0-3]	**1 pt**	**LSS nutrition scale [0-100]**	**7 pts**	**4.44 (1.74-11.35)**	**0.002**
	NIH lower GI score [0-3]	1 pt	LSS nutrition scale [0-100]	7 pts	0.91 (0.27-3.05)	0.878
Eye	**NIH eye score [0-3]**	**1 pt**	**LSS eye scale [0-100]**	**15 pts**	**3.39 (1.98-5.82)**	**<0.0001**
	NIH eye score [0-3]	**1 pt**	**Worst eye compliant [0-10]**	**2 pts**	**2.35 (1.33-4.15)**	**0.003**
Lung	FEV1%	10%	LSS lung scale [0-100]	8 pts	0.90 (0.43-1.87)	0.779
	NIH lung score [0-3]	**1 pt**	**LSS lung scale [0-100]**	**8 pts**	**2.81 (1.70-4.65)**	**<0.0001**
Overall	**NIH responder [CR+PR] vs. nonresponder**		**LSS summary scale [0-100]**	**7 pts**	**1.89 (1.17-3.06)**	**0.010**
	NIH responder [CR+PR] vs. nonresponder		**Overall cGVHD [0-10]**	**2 pts**	**2.37 (1.48-3.77)**	**<0.001**
	Overall severity [0-10]	**2 pts**	**LSS summary scale [0-100]**	**7 pts**	**1.84 (1.08-3.11)**	**0.024**
	Overall severity [0-10]	**2 pts**	**Overall cGVHD [0-10]**	**2 pts**	**3.46 (2.17-5.52)**	**<0.0001**
Pt, point; LSS, Lee symptom scale; GI, gastrointestinal; P-ROM, photographic range of motion						

About cGVHD

cGVHD is a complication that can occur following allogeneic stem cell transplantation, resulting in significant morbidity and mortality. In cGVHD, transplanted immune cells (graft) attack the patient's cells (host), leading to inflammation and fibrosis in multiple tissues, including skin, mouth, eye, joints, liver, lung, oesophagus and gastrointestinal tract. Approximately 14,000 patients in the United States are living with cGVHD.

About Rezurock® (belumosudil)

Rezurock® (belumosudil) is the first and only approved therapy inhibiting Rho-associated coiled-coil kinase 2 (ROCK2). Rezurock is approved in the United States for the treatment of adult and pediatric patients 12 years and older with cGVHD after failure of at least two prior lines of systemic therapy. For more information, visit www.Rezurock.com.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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Sanofi Forward-Looking Statements
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates regarding the marketing and other potential of the product, or regarding potential future revenues from the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although

Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.