

The roxadustat wrangling rumbles on



Amy Brown

Fibrogen and partners were probably hoping that [the long-awaited cardiovascular safety analysis](#) of the huge roxadustat clinical programme would silence concerns. But another highly critical report emerged yesterday; the authors are probably positioned to benefit from falling share prices, but it is notable that both Fibrogen and Astrazeneca moved to defend their data. The report concluded that roxadustat was unlikely to win approval in dialysis-dependent patients, pointing out that Pyrenees, a major trial that had the worst safety reading, had been omitted from the pooled analysis; it also claimed that the way the data were analysed understated the risk of death in this setting. Astrazeneca responded by saying the FDA had agreed to the Pyrenees exclusion, because of its different design; supportive equity analysts moved to defend other assertions of opaqueness. The sellside remains largely approving of Fibrogen, but roxadustat forecasts have come down substantially over the past 12 months. None of these debates will be settled until the regulatory verdicts are known, later next year, and until then many investors might decide to believe that there is no smoke without fire. Substantial postmarketing requirements are surely the best-case scenario here.

Sales forecasts for roxadustat, and how they've changed

Company	Markets	2020e (\$m)	2024e (\$m)	12-mth chg in 2024 forecast
Astrazeneca	WW ex Astellas regions, China co-promote with Fibrogen	160	893	-31%
Astellas Pharma	Japan, Europe, CIS, Middle East & South Africa	86	387	-47%
Fibrogen	WW royalties, China co-promote with Astra	32	155	-42%
	Total sales	278	1,436	

Source: EvaluatePharma.

Phase III roxadustat programme for US and EU regulators

Study	Primary sponsor	Comparator	Location
Dialysis dependent			
Himalayas*	Fibrogen	Epogen	US, Europe, RoW
Sierras*	Fibrogen	Epogen	US, RoW
Rockies*	Astrazeneca	Epogen	US, Europe, RoW
Pyrenees	Astellas	Epogen or Aranesp	EU only
Non-dialysis dependent			
Andes*	Fibrogen	Placebo	US, RoW
Olympus*	Astrazeneca	Placebo	US, Europe, RoW
Alps*	Astellas	Placebo	Europe, RoW
Dolomites	Astellas	Aranesp	Europe, RoW
<i>*Included in Mace analysis for US FDA.</i>			

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