

# Medivir

## Q2-2016 Conference call

17 August, 2016

Niklas Prager CEO  
Ola Burmark CFO  
Richard Bethell CSO

The logo features the word "MEDIVIR" in a bold, blue, sans-serif font. It is enclosed within a blue rectangular frame that has a slight 3D effect, with a horizontal line above and below the text, and a vertical line on the left side.

**MEDIVIR**

A research-based  
pharmaceutical company  
with focus on oncology  
and infectious diseases

## Q2 Highlights

### Creating two independent companies

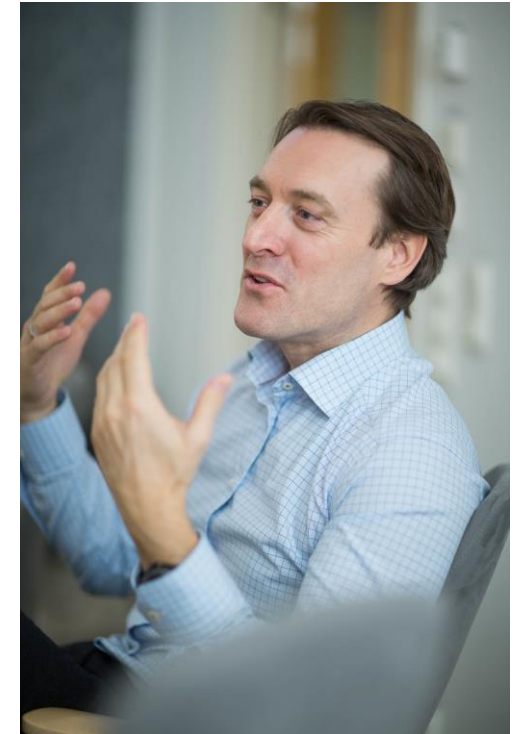
- The Board of Directors have tasked the company management with reviewing the possibility of dividing the company's operations into two independent companies and achieving a separate listing for the commercial pharmaceutical portfolio.
- The objective is to highlight the value of both the commercial operations and the pharmaceutical projects that make up the R&D portfolio. In addition, the separation of the businesses would enable the existing operations to be conducted by two clearly focused, specialised companies where both companies' potential can be maximised in line with their different objectives and capabilities.

### Global Net Sales of OLYSIO® of USD 43m generating a royalty of SEK 24m

- Nordic Olysio sales reached SEK 5.6m.

### Simeprevir data presented at EASL

- New clinical data for simeprevir were presented in April by our partner Janssen at the 2016 International Liver Congress of the European Association for the Study of the Liver (EASL). A total of nine presentations were made, including one "late breaker" presentation.
- In May, Medivir's partner Janssen Research & Development, LLC., decided to initiate a phase IIb study to investigate the efficacy, safety and pharmacokinetics of different treatment regimens of AL-335, odalasvir, and simeprevir in treatment-naïve and treatment-experienced patients with chronic Hepatitis C Virus (HCV) genotype 1-6 infection, with and without cirrhosis.



## Significant Events After Second Quarter

### Outlicensing deal for MIV 802 finalized

- Today we announced that TREK Therapeutics (TREKtx) has licensed the exclusive rights to develop and commercialize MIV-802 globally, excluding China, Taiwan, Hong Kong and Macau. MIV-802 is a nucleotide polymerase inhibitor under development for the treatment of hepatitis C virus (HCV) infection.
- TREKtx is developing combination treatments for HCV utilizing its portfolio of antiviral agents including faldaprevir, a protease inhibitor, TD-6450, a NS5A inhibitor, and lomibuvir, a non-nucleoside NS5B inhibitor.
- Medivir is entitled to receive milestones based on successful clinical development and royalties capped at a mid-teens percentage upon commercialization of MIV-802 containing products.
- BioPhausia, a subsidiary of Medivir, is granted options to commercialize MIV-802 containing products in the Nordics and certain Western European countries.



**TREK**  
THERAPEUTICS

# Financial summary

## Summary of Group's figures (SEK m)

	Q2		Six Month	
	2016	2015	2016	2015
Net turnover	81.3	245.8	156.3	461.7
Gross profit	55.7	214.9	110.4	397.7
EBITDA	-40.1	104.9	-72.4	189.6
Operation profit (EBIT)	-48.1	96.1	-88.9	172.2
Profit/loss before tax	-43.6	85.4	-81.7	168.2
Profit/loss after tax	-39.8	64.1	-80.2	130.7
Operating margin, %	-59.2%	39.1%	-56.9	37.3
Basic earnings per share	-1.48	2.29	-2.98	4.50
Diluted earnings per share	-1.47	2.27	-2.97	4.46
Net worth per share	50.8	55.7	50.8	55.7
Return on Equity	-3.1%	5.8%	-5.8	9.7
Cash flow from operating activities	-37.1	64.3	-73.5	269.6
Liquid assets and ST investments	997.5	1 043.4	997.5	1 043.4
R&D spending/total opex, %	71.5%	60.2%	73.0%	61.1%

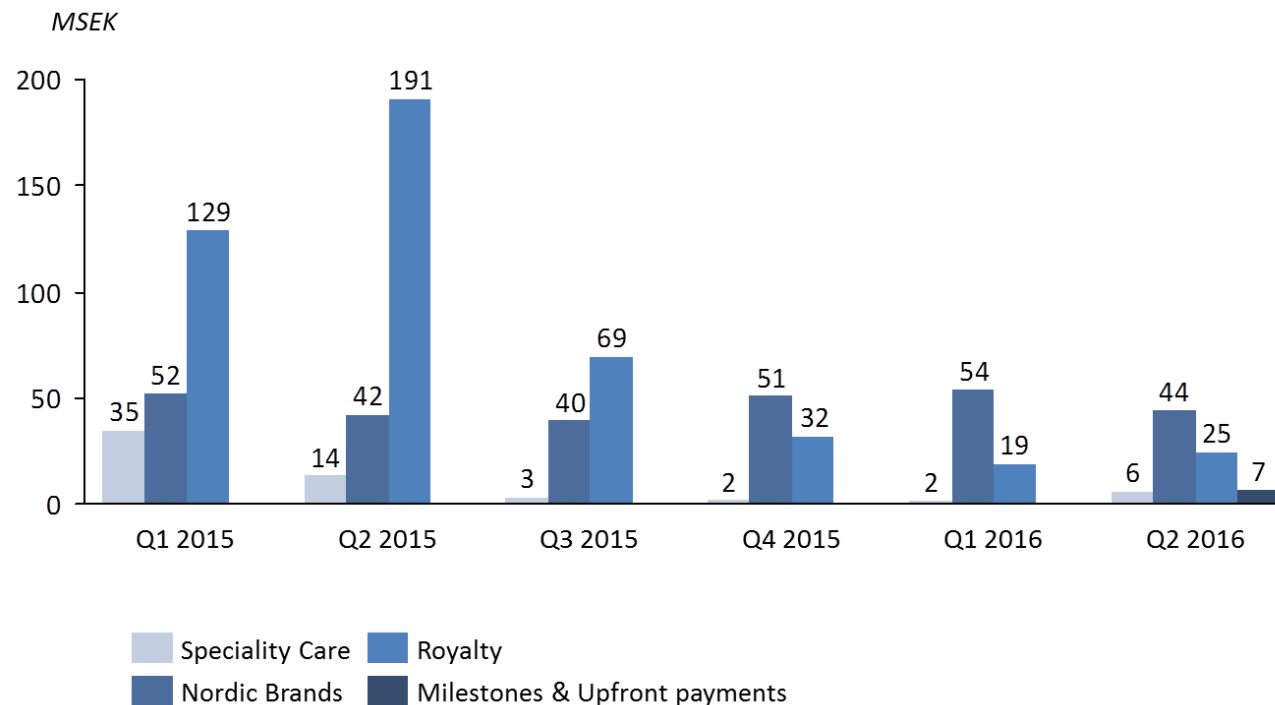
## Q2 Net turnover

- Net turnover totalled SEK 81.3m (245.8m), of which SEK 24.2m (190.7m) comprised second quarter royalties for simeprevir.
- Revenue from Medivir's own pharmaceutical sales totalled SEK 51.5m (55.1m), of which 44.5 million (41.9 m) was generated by the Nordic Brands portfolio. The Innovative Specialty Care portfolio achieved sales of 5.7 million (13.5 m).

## Q2 Key figures

- Operational loss (EBIT) was -48.1m (104.9)
- The loss after tax was SEK -39.8m (64.1m)
- Basic and diluted earnings per share totalled SEK -1.48 (2.29) and SEK -1.47 (2.27), respectively
- The cash flow from operating activities amounted to SEK -37.1m (64.3m)
- Liquid assets and ST investments amounted to SEK 997.5m (1 043.4)

# Breakdown of net turnover



## Pharmaceutical sales

- Nordic net sales totalled SEK 50.1 million, of which SEK 5.6 million derived from sales of OLYSIO®
- Nordic Brands sales totalled SEK 44.4 million (41.6), representing 6.7% growth vs. same quarter last year. Seasonal variations are driven by Mollipect sales, which are driven by the timing and intensity of the flu season

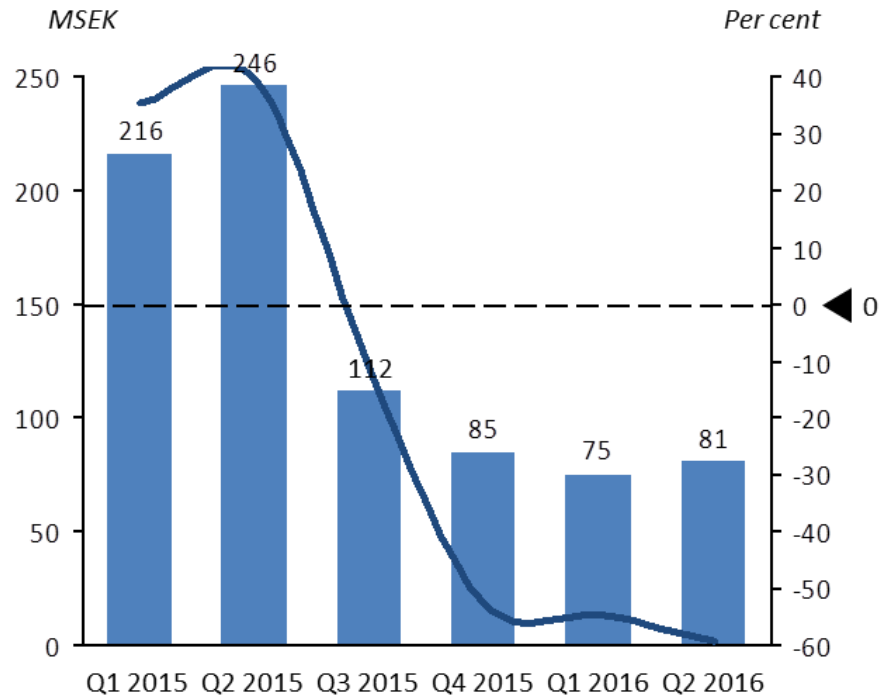
## Royalties and Milestones

Royalty income totalled SEK 24.7m (190.7), a decline of SEK 166.0m

- Janssen’s global net sales of simeprevir amounted to USD 43m, whereof US net sales were USD 20.8m and RoW USD 21.9m

SEK 6.5m in milestones were received, following registration of the product Zoviduo/Xerclear in Spain by our partner GSK

# Operating income and margin



## Gross Profit

- The gross profit amounted to SEK 55.7m, corresponding to a decrease of SEK 159.2m and equating a gross margin of 68% (87%), explained by the decline in royalties

## Operating Expenses

- Selling expenses decreased by SEK -10.0m compared to the same quarter last year
- Administrative expenses decreased by SEK -6.1m.
- Research and development costs increased by SEK 2,8m, primarily as a result of the ongoing phase IIa study of MIV-711
- Other operating income/expenses are positive and increased by SEK 1.6m, largely due to exchange rate effects
- Overall, operating expenses totaled SEK -103.8m (-118.7 m), corresponding to a decrease of SEK 14.9m

## Operating Loss

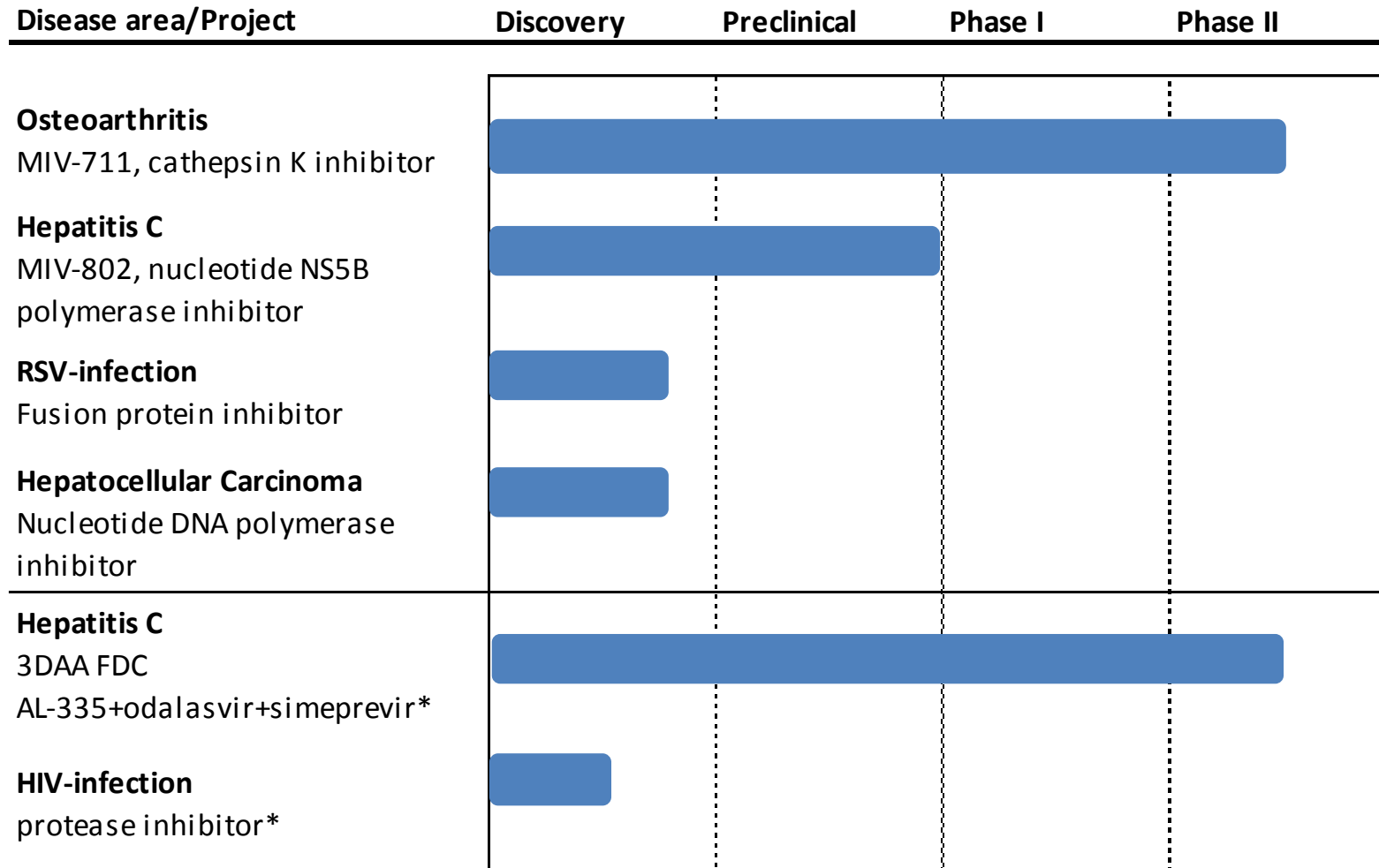
- Operating loss totaled SEK -48.1m (96.1), corresponding to a decrease of SEK 144.2m



# Research & Development



# Medivir R&D Pipeline



\* Partner Janssen



# Protease Inhibitor Portfolio: Simeprevir

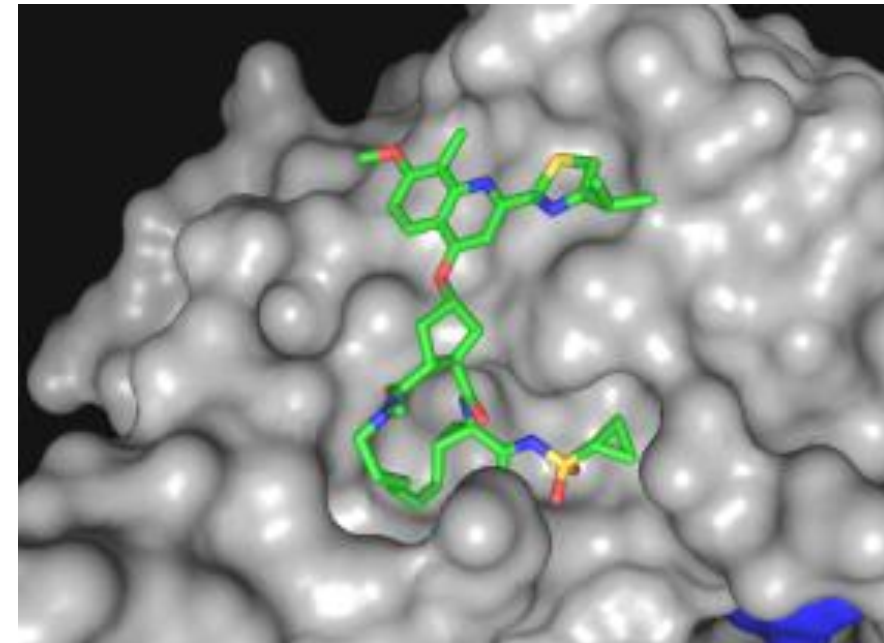
## Hepatitis C

In August we announced that the Phase IIa clinical trial to evaluate the combination of simeprevir, the NS5A inhibitor odalasvir and the nucleotide analogue AL-335 in continues to progress

- Interim safety, tolerability and efficacy (SVR12) data will be presented at the EASL-AASLD special conference on HCV in Paris, September 23<sup>rd</sup> and 24<sup>th</sup>
  - Treatment-naive, genotype 1 patients
  - Treatment durations of eight weeks or less
- Trial due to be completed by end 2016
- [www.clinicaltrials.gov/ct2/show/NCT02569710](http://www.clinicaltrials.gov/ct2/show/NCT02569710)

Janssen has announced its intention to run a Phase IIB clinical trial to further investigate the efficacy, safety and pharmacokinetics of this triple regimen in different patient populations

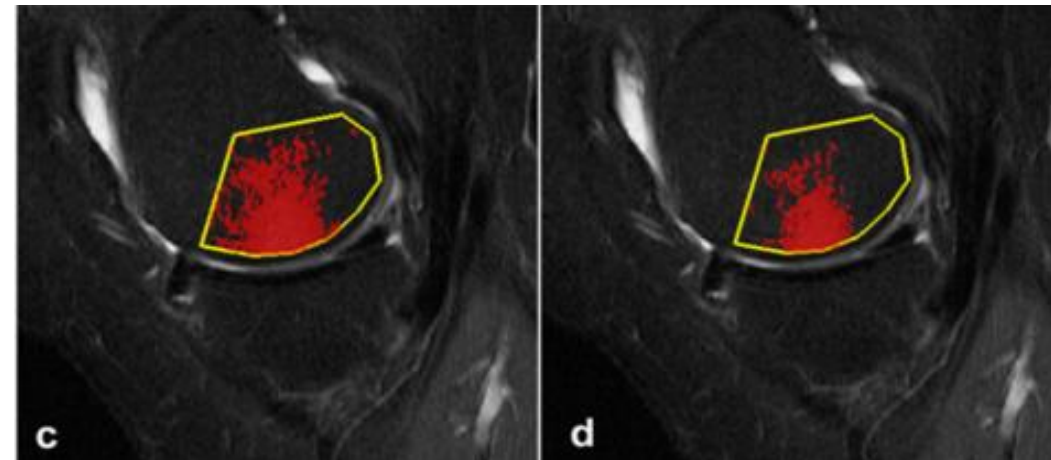
- [www.clinicaltrials.gov/ct2/show/NCT02765490](http://www.clinicaltrials.gov/ct2/show/NCT02765490)



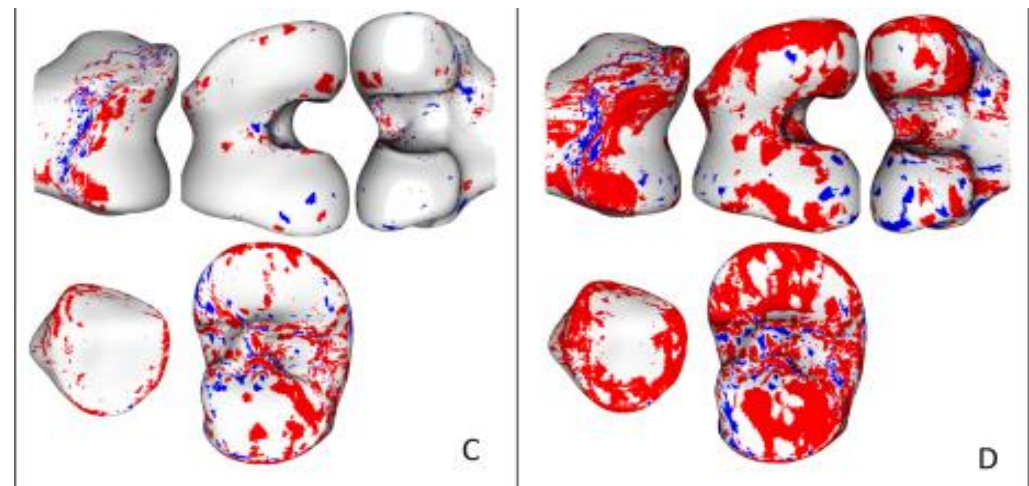
# Protease Inhibitor Portfolio: MIV-711

## MIV-711 201

- The phase IIa study of MIV-711 in patients with moderate knee osteoarthritis was initiated early in the first quarter  
[www.clinicaltrials.gov/ct2/show/NCT02705625](http://www.clinicaltrials.gov/ct2/show/NCT02705625)
- First patient enrolled into the study in January
- All clinical sites are now recruiting patients, and well over half the target number of patients are receiving study medication
- We continue to expect to present the results from the study in the second half of 2017



Picture modified from: Nielsen FK et al. BMC Musculoskeletal Disorders 2014, 15:447



Picture modified from: Bowes MA, et al. Ann Rheum Dis 2015;74:519–525

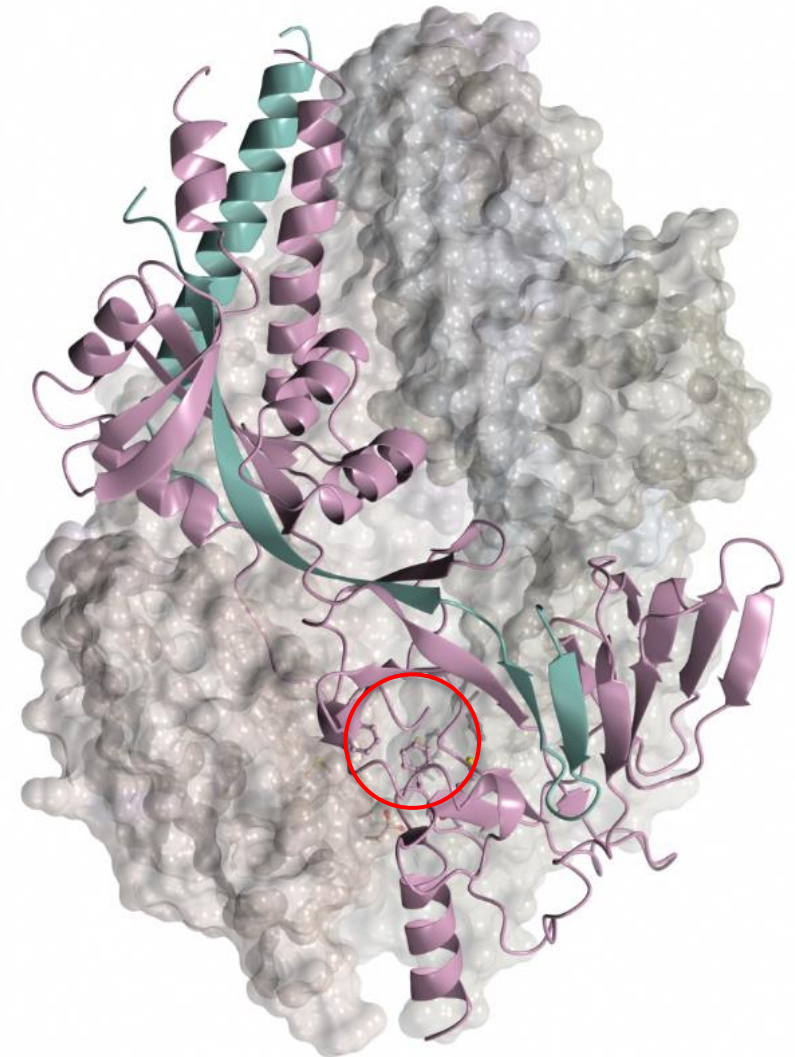
# RSV Fusion Inhibitor Project Update

## Project Background:

- RSV F protein drives fusion between the RSV envelope and host cell membranes, which is essential for entry of the virus into host cells
- No cellular counterpart of RSV F protein and no shared homology with cellular proteins
- Small molecules targeting RSV F protein have demonstrated antiviral activity in tissue culture, animal models (rodent, primate, bovine), and clinical efficacy in humans
- Medivir’s fusion inhibitors are “triggering antagonists”, stabilizing F to prevent the release of the fusion peptide

## Project Update:

- Highly potent compounds active against diverse RSV strains identified ( $EC_{50} < 1nM$ )
- These compounds also have favourable preclinical PK, including good oral bioavailability plasma half-lives
- First public presentation of the project expected at a scientific meeting later this year



# Hepatocellular Carcinoma Nucleotide Project Update

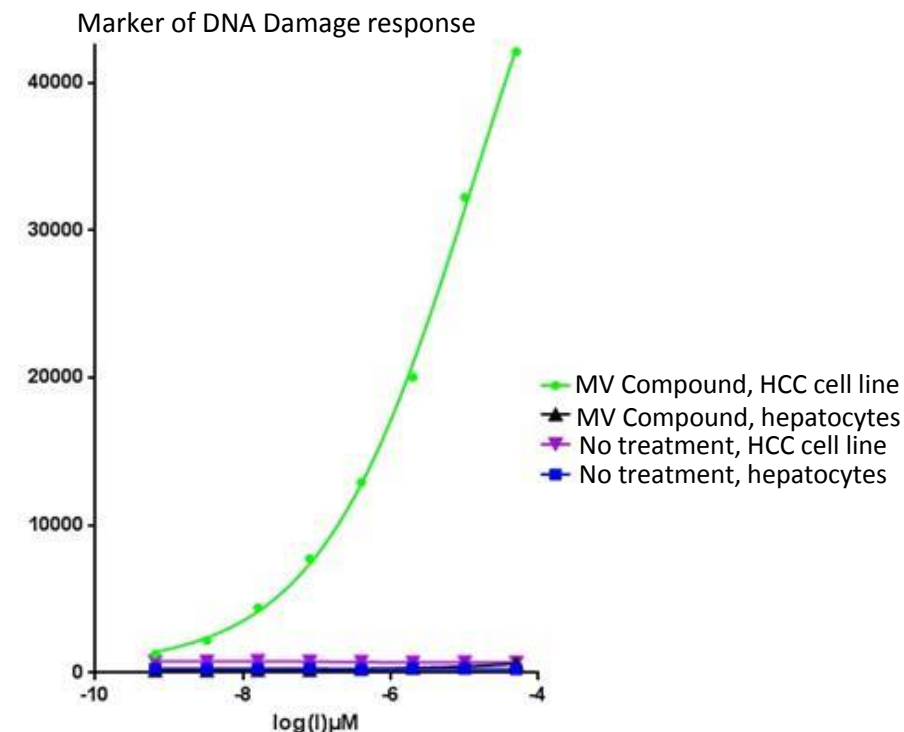
## Project Background:

- Starting point is a known nucleoside analogue that is active in preclinical cancer models, but failed in clinic due to systemic dose limiting toxicities
- Not a substrate for enzymes conferring resistance to other nucleoside analogues
- Novel compounds synthesized using Medivir technology to enable directed delivery to the liver
  - Aim to improve activity and safety

## Project Update:

- Compounds with substantially enhanced activity against HCC cell lines, and selectivity relative to non-cancerous hepatocytes, have been identified
- These compounds also have biological profiles known to result in selective targeting to the liver
- Compounds synergistic with sorafenib, the current standard of care for advanced HCC
- First public presentation of the project will be made at the 10<sup>th</sup> Annual Conference of the International Liver Cancer Association (September):

<http://ilca2016.org/>





# Q&A



A blue L-shaped graphic consisting of a vertical line on the left and a horizontal line on the top, forming the top-left corner of a square.

[www.medivir.com](http://www.medivir.com)

**Ticker: MVIR**

**Exchange: OMX / NASDAQ**

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