

The background of the slide features a complex, abstract molecular structure. It consists of numerous interconnected nodes, represented by small spheres in shades of red, white, and blue, connected by thin, light-colored lines. The overall appearance is that of a network or a crystalline lattice, set against a dark blue gradient background. The text is overlaid on this background.

**MEDIVIR ENTERS INTO EXCLUSIVE LICENSING  
AGREEMENT WITH IGM BIOSCIENCES FOR  
BIRINAPANT**

**January 12, 2021**

**MEDIVIR**

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# Today's presenters



Yilmaz Mahshid

President and CEO  
Medivir



Fred Schwarzer

President and CEO  
IGM Biosciences



Fredrik Öberg

Chief Scientific Officer  
Medivir

# Executive summary

## Proprietary clinical asset

- MIV-818 – A liver directed nucleotide prodrug
- In phase Ib clinical development
- Opportunities for breakthrough oncology indications

## The company

- Focus on clinical development in unmet oncology indications
- Resolved to carry out a preferential rights issue of c. SEK 170 million

## Multiple clinical programs for partnering/out-licensing

- Remetinostat and MIV-711

Founded: 1988

Listed: Nasdaq OMX

Location: Stockholm

Cash position: c. SEK 83M<sup>1)</sup>

Market Cap: c. SEK 200M<sup>2)</sup>

FTE: 9

1) Q3 report

2) 2021-01-11 (c. USD 25M)

## Focused clinical program

Nucleotide prodrug	Indication	Research	Preclinical	Phase I	Exclusivity
MIV-818	Liver cancer				IP : 2035

## Partnered assets in clinical development

Compound	Mechanism	Indication	Phase I	Phase II	Partner	Exclusivity
Birinapant	SMAC mimetic	HNSCC <sup>2)</sup>				IP : 2034

## Multiple clinical programs for partnering/out-licensing

Compound	Mechanism	Indication	Phase I	Phase II	Phase III	Exclusivity
Remetinostat	Topical HDAC	MF-CTCL <sup>1)</sup> BCC				IP : 2034
MIV-711	Cathepsin K inhibitor	OA <sup>3)</sup>				IP : 2034

1) Indications: basal cell carcinoma, squamous cell carcinoma, mycosis fungoides cutaneous T-cell lymphoma (phase III ready)

2) Head and neck squamous cell carcinoma

3) Osteoarthritis

# Licensing agreement with IGM Biosciences

- Medivir and IGM Biosciences (IGM) have entered into an exclusive licensing agreement for birinapant
- IGM is a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies
- IGM will receive global development rights for birinapant, a clinical-stage SMAC mimetic that binds to and degrades Inhibitors of Apoptosis Proteins (IAPs), leading to cell death in tumor cells
- Birinapant is initially intended to be combined with IGM-8444, an IgM antibody targeting Death Receptor 5 (DR5) being developed by IGM, and birinapant has been shown to enhance anti-tumor activity preclinically



# Licensing agreement with IGM Biosciences

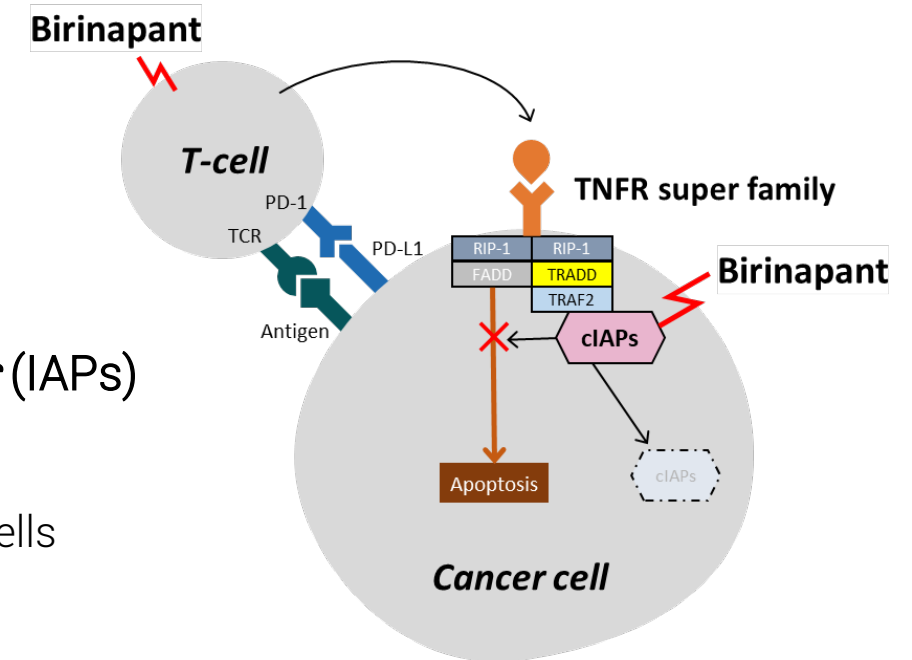
- Medivir will receive an upfront payment of USD 1 million upon signing the agreement, followed by an additional USD 1.5 million when birinapant is included by IGM in a clinical phase I study
- Should birinapant be successfully developed and approved, Medivir is entitled to receive development, regulatory and sales milestone payments up to a total of approximately USD 350 million plus tiered royalties from the mid-single digits up to mid-teens on net sales

# Birinapant

- Birinapant was acquired from TetraLogic Pharmaceuticals Corporation (TetraLogic) in 2016 and has since then been developed by Medivir
- Medivir recently renegotiated the original agreement with TetraLogic so that the compensation Medivir is obliged to pay in connection with a licensing agreement is based on the distribution of actual future revenues to Medivir
- In accordance with the recently announced revised agreement with Tetralogic, they will receive a share of future birinapant revenues

# Birinapant – Mechanism of Action

- Birinapant is a potent *iv* administered bivalent SMAC mimetic
- Birinapant binds to and degrades *Inhibitors of Apoptosis Proteins* (IAPs)
  - (i) IAP genes are often amplified/over-expressed in cancers
  - (ii) Birinapant enables apoptosis (programmed cell death) in tumor cells
  - (iii) Birinapant activates the immune system to attack the tumor
- Significant anti-tumor activity demonstrated in multiple preclinical models as single agent and in different combinations
- Birinapant shows potent degradation of cIAPs in preclinical models and in patient tumors in clinical trials



# Birinapant - Clinical Experience in Oncology

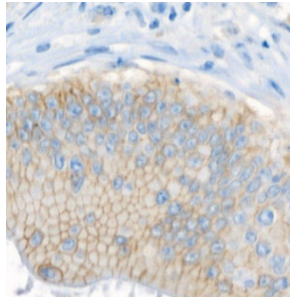
Patients treated	Clinical trials in oncology	Combinations in clinical trials	Open INDs
440	10+	chemotherapy, molecularly targeted drugs, radiation, immune-therapy	3

- Birinapant has been generally well tolerated. Most adverse events were dose-related, transient and mild or moderate in severity – large safety database
- Our recent clinical trial with the combination of birinapant with Merck’s Keytruda® (anti-PD1) demonstrated the feasibility of combining with antibody therapies
- Bivalent Smac-mimetics such as birinapant are potentially more effective in degrading cIAP1 in TNF-receptor superfamily complexes compared with monovalent Smac-mimetics
- The future for birinapant lies in finding the right combination with therapies that can maximize the synergy with Birinapant-induced degradation of cIAPs

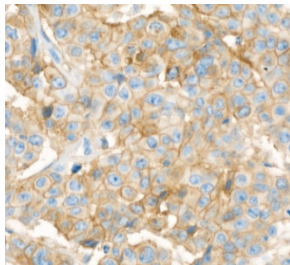
# TNFr Superfamily: Trimerizing Agonists

Examples of TNFr agonism: inducing Death Receptor 5 based cell killing

## DR5 Expression

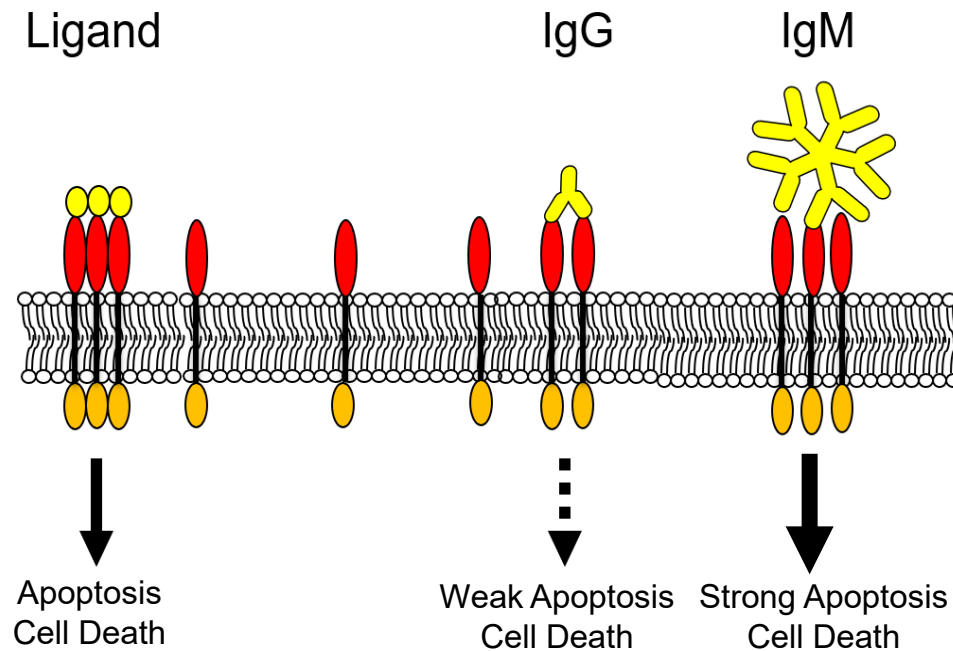


Colon Adenocarcinoma



Gastric Adenocarcinoma

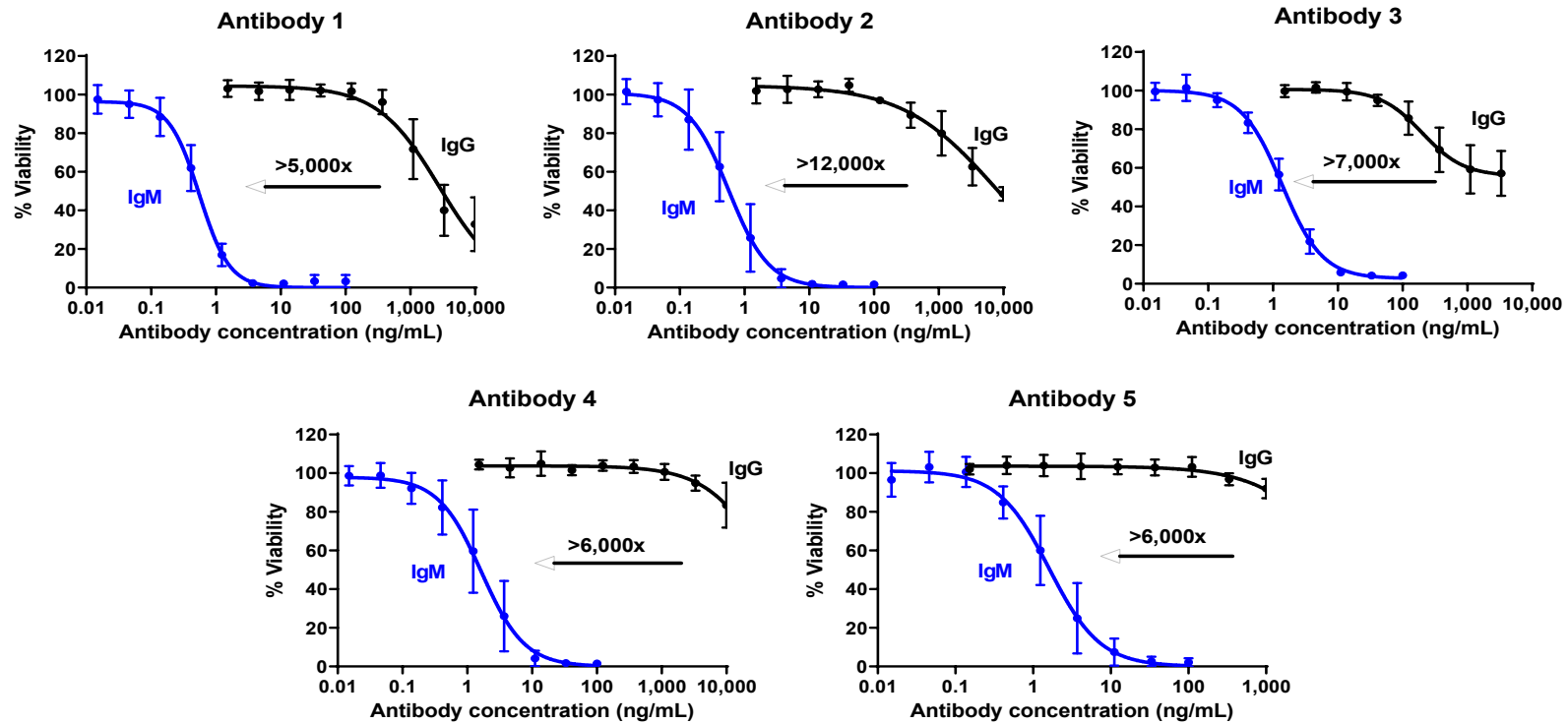
Also: pancreatic, lung, breast and prostate tumors, leukemia and lymphoma



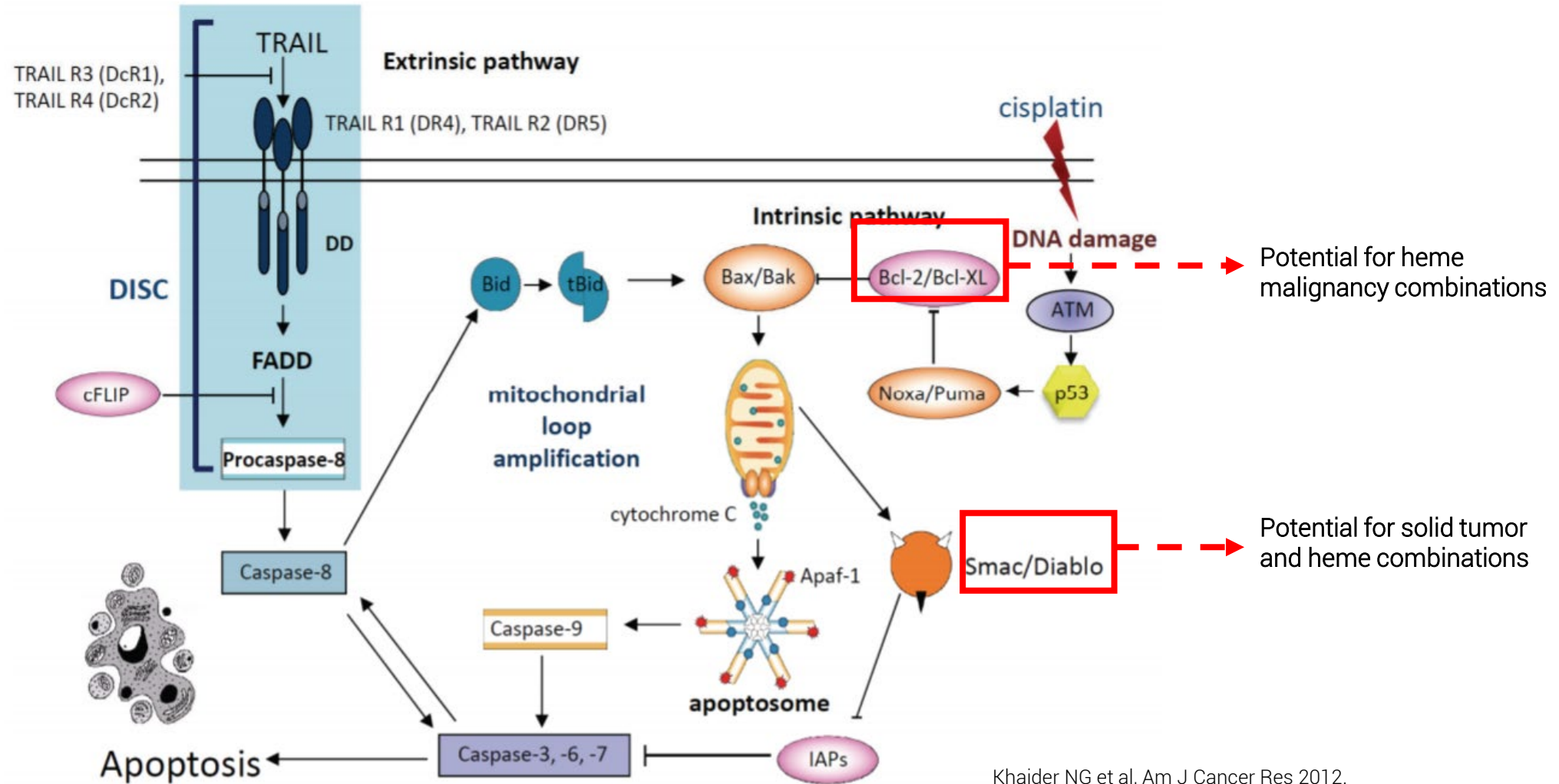
TNFr: tumor necrosis factor receptor

# DR5: IgM Superior *In Vitro* to IgG

Cell line killing comparison *in vitro* of IgG and IgM DR5 antibodies with five different binding domains



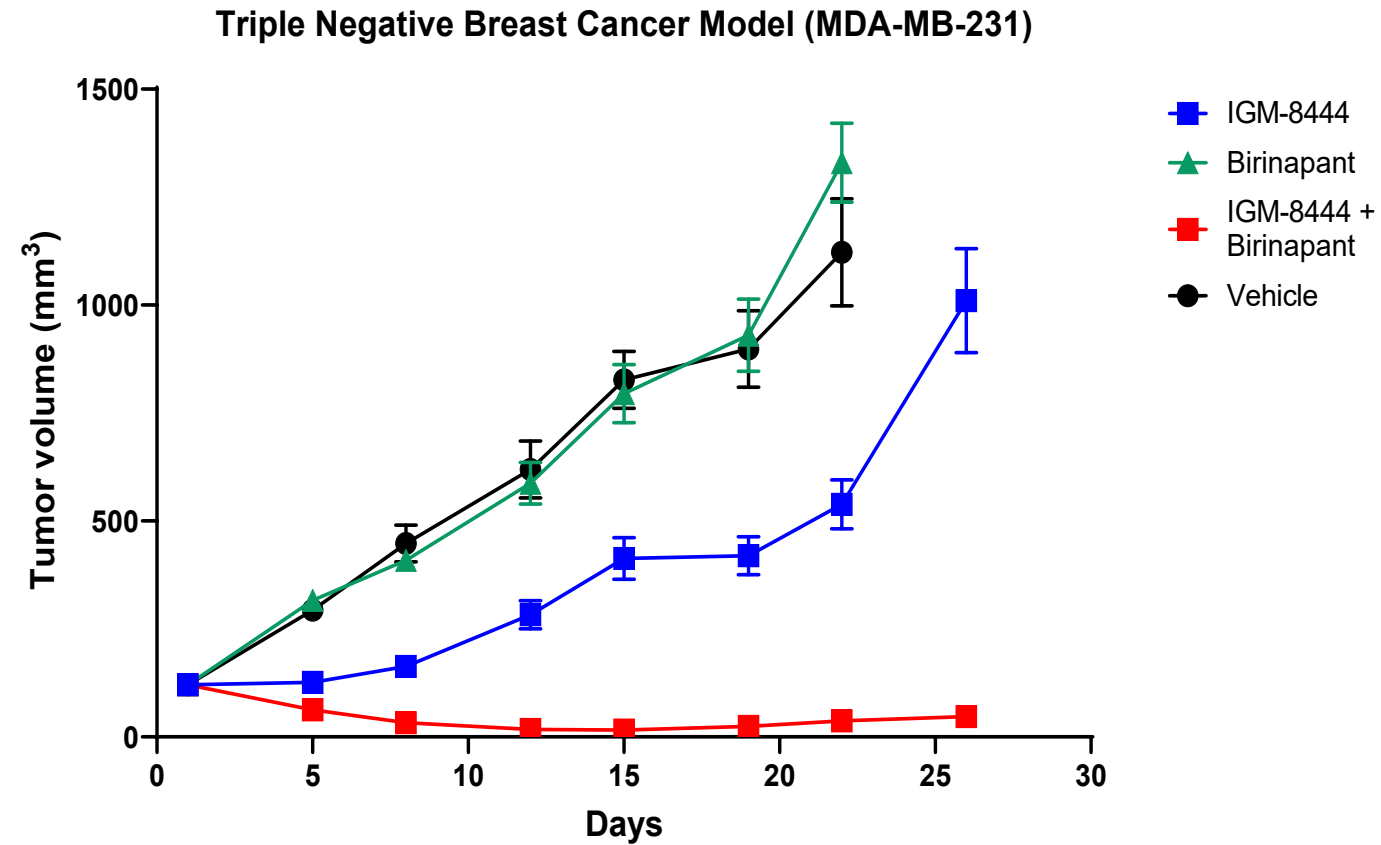
# Rationale for combining IGM-8444 with pro-apoptotic agents



Khaidar NG et al, Am J Cancer Res 2012.

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# DR5: IGM-8444 *In Vivo* Combination with Birinapant



IGM-8444 (5 mg/kg Q2D x 11); Birinapant (2.5 mg/kg Q3D x 7)



QA