

# Oncology acquisition transaction

## Investor call

November 3, 2016

Niklas Prager CEO

Richard Bethell CSO

Ola Burmark CFO

The logo for Medivir, featuring the word "MEDIVIR" in a bold, blue, sans-serif font. The text is enclosed within a blue rectangular frame that has a slight 3D effect with a shadow on the right side.

# MEDIVIR

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

**Signed agreement to acquire two clinical stage programs from US-based company Tetralogic Pharmaceuticals**

**Portfolio Transformation:** Results in balanced and broad pipeline from early to late stages of development

- Shift of balance in the pipeline from research to later stage development
- Enables Medivir to build a critical mass in development
- Secures visible value generation by Medivir as a separate R&D company, with expected near-term and continuous news flow from clinical pipeline

**Corporate Transformation:** Transition to oncology-focused R&D company

- Both acquired programs in targeted oncology indications with high unmet need
- Aligned with the previously announced R&D focus



# Why This Transaction is Right for Medivir

## Strategy for Value Creation



### Meaningfully advances achievement of stated objectives

**Strengthen the R&D pipeline**



- Advance and expand the pipeline with two clinical stage programs
- Strengthens and accelerates Medivir's oncology focus
- Highly complementary to Medivir's technology platforms

**Collaborate through global partnerships**

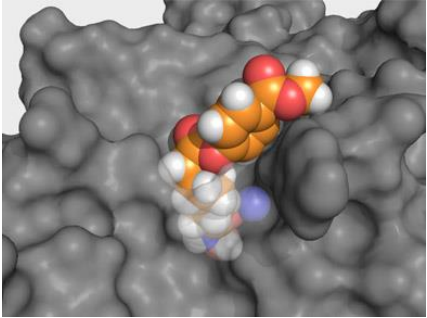
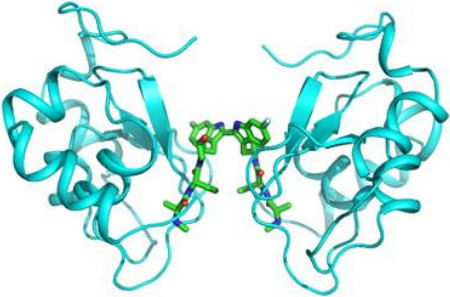




- Merck collaboration with Tetralogic to study Keytruda in combination with birinapant

**Invest capital responsibly**



- Structure heavily weighted toward milestones and royalties based on future project success while providing a reasonable upfront payment
- Portfolio diversification with two clinical programs, and potential additional future indications for each

| Compound   | Clinical Stage  | Indication   | Mechanism   |
|--|---|--|---|
| <p><b>remetinostat</b></p>  | <p>Phase II</p> <p><b>Link to Medivir platform:</b><br/>HDACs are a group of enzymes closely related to proteases</p>   | <p>Early stage cutaneous T-cell lymphoma (CTCL, an orphan hematologic cancer)</p>  | <p>Topical, skin-directed inhibitor of histone deacetylases (HDACs)</p>   |
| <p><b>birinapant</b></p>  | <p>Phase I</p> <hr/> <p>Phase II</p> <p><b>Link to Medivir platform:</b> Peptidomimetic, like simeprevir, and with a strong link to Medivir's current interests in protein ubiquitylation</p> | <p>Various solid tumors (combination with Keytruda) </p> <hr/> <p>High-grade serous carcinomas (including ovarian cancer) </p> | <p>Bivalent second mitochondrial activator of caspases (SMAC) mimetic, an inhibitor of apoptosis proteins (IAP) inhibitor</p> |

## Process

**Medivir identified Tetralogic as an attractive target 2 years ago; Tetralogic's current financial situation made a transaction possible**

- **Disappointing trial results** January 2016 with birinapant in myelodysplastic syndrome (Phase II)
  - Medivir sees a much stronger rationale in other oncology indications
- **Liquidity difficulties** with convertible debt outstanding and inability to raise capital
- **Hired financial advisor** to look at strategic alternatives for the company

## Medivir differentiators

**Medivir was uniquely positioned to recognize the value of both clinical assets**

### **Remetinostat:**

- Oncology not dermatology
- Medivir experience in topical therapeutic development (Xerclear) and chemistry-driven targeting of therapies to specific tissues (e.g. liver targeting)

### **Birinapant:**

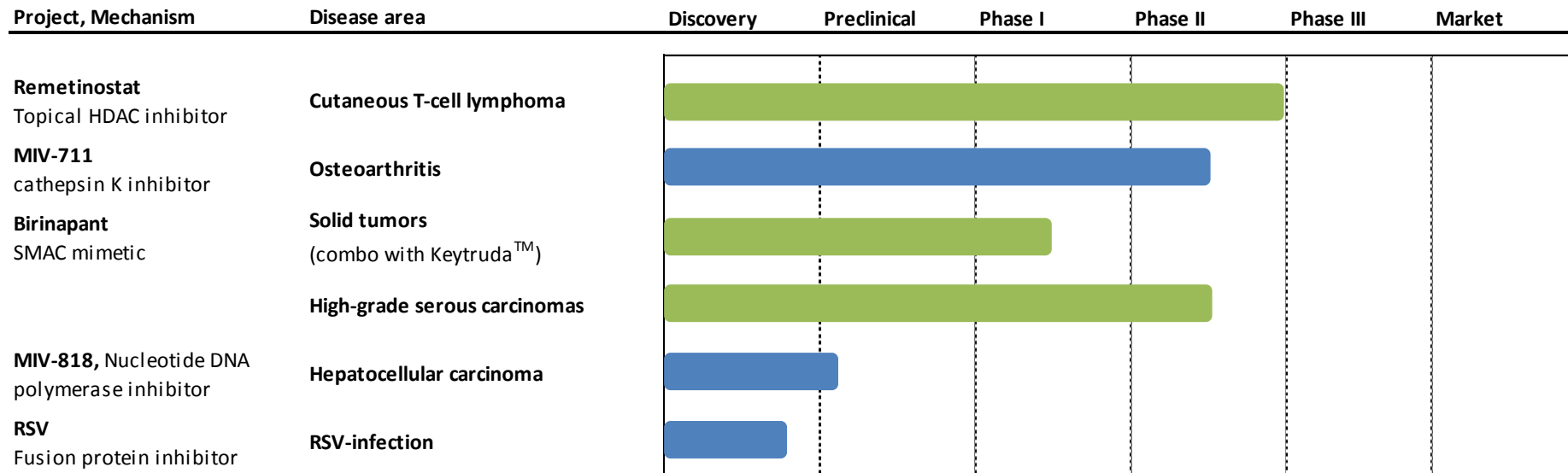
- Medivir's scientific platform in protease inhibition and interests in ubiquitylation provide us unique insight into future development for birinapant

**Identified opportunities in other oncology indications for both assets**

# Medivir R&D pipeline after transaction is diversified from early to late stages of development

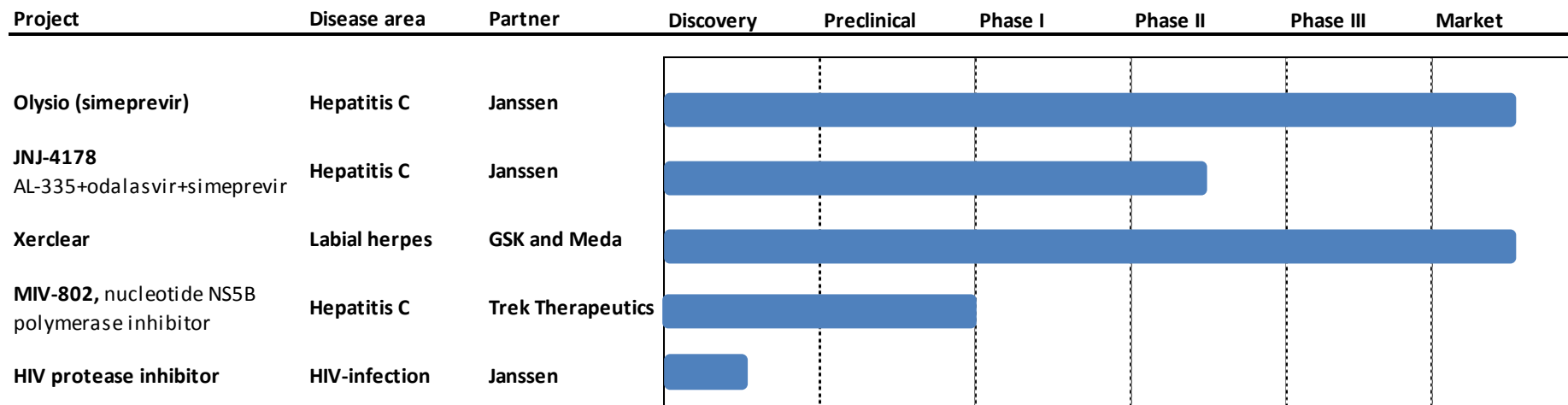


## Proprietary Pipeline



Well-balanced and broad pipeline from early to late stages of development

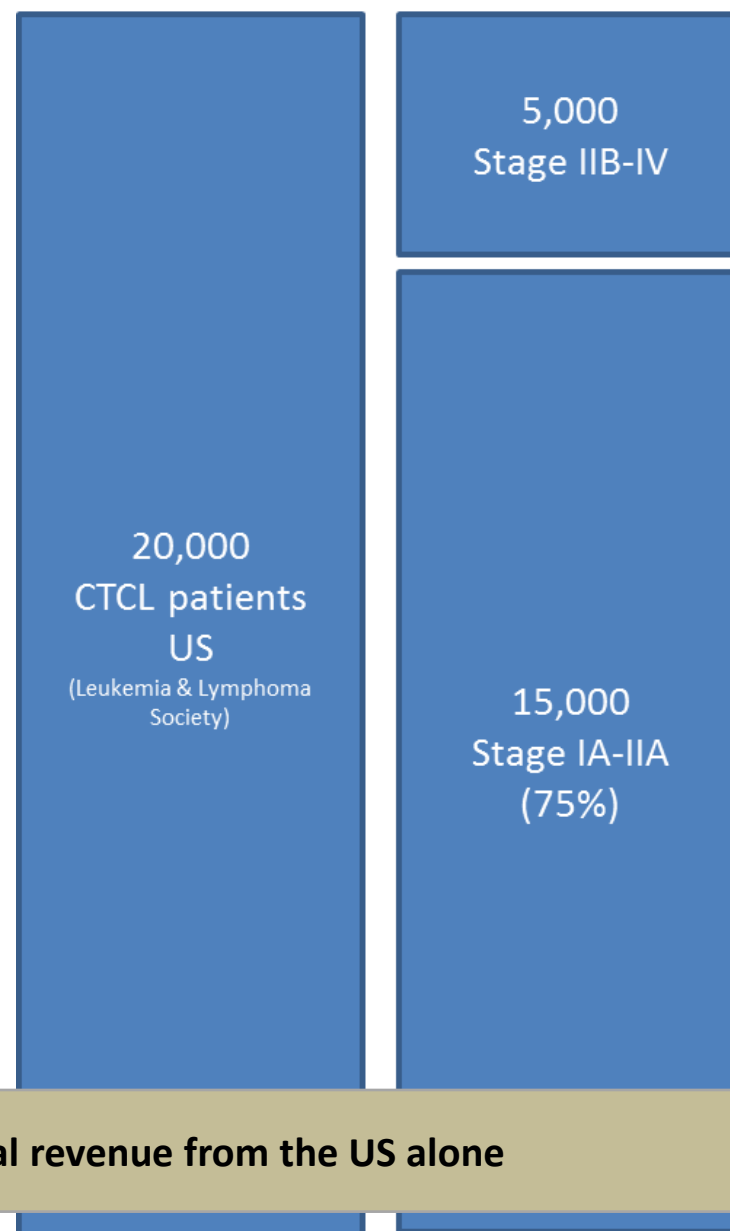
## Partnership Pipeline



Partnerships where they can meaningfully enhance the value of a project

## CTCL: orphan cancer disease with a meaningful market opportunity

- Cutaneous T-cell lymphoma (CTCL) is an orphan disease in both the US and Europe
  - Annual incidence of 1,000-3,000
  - Estimated prevalence in the US of ~20,000 and similar in EU5
- Approximately 75% of CTCL constitute early stage IA-IIA disease
- Stage IA-IIA is predominantly indolent, with patients remaining in this stage of disease for an extended period
- Expected \$900 million addressable market in the US for early-stage CTCL



**A 15% patient share would translate into over 1 BSEK in annual revenue from the US alone**

## Early-stage CTCL: Patients and physicians looking for new treatment options

### Disease background

- **In early stages of CTCL the disease is confined to the skin (Photos A-E)**
  - Stage IA involves <10% of skin
  - Stage IB involves >10% of skin
  - Stage IIA has stage IA or B skin involvement with additional limited involvement of lymph nodes
- **Patients remain in this stage for an extended period and require long-term treatment**
- **Significant quality of life issues, including clinically significant pruritus (itch)**

### Limitations of current treatments

- **Rotation among treatments with no single treatment for long-term use**
  - 1st line treatment with topical steroids
  - Current 2nd line treatments lack sustained efficacy and/or tolerability and are highly irritating



**Room for an additional option for patients in rotation with, after, and in combination with other treatments**

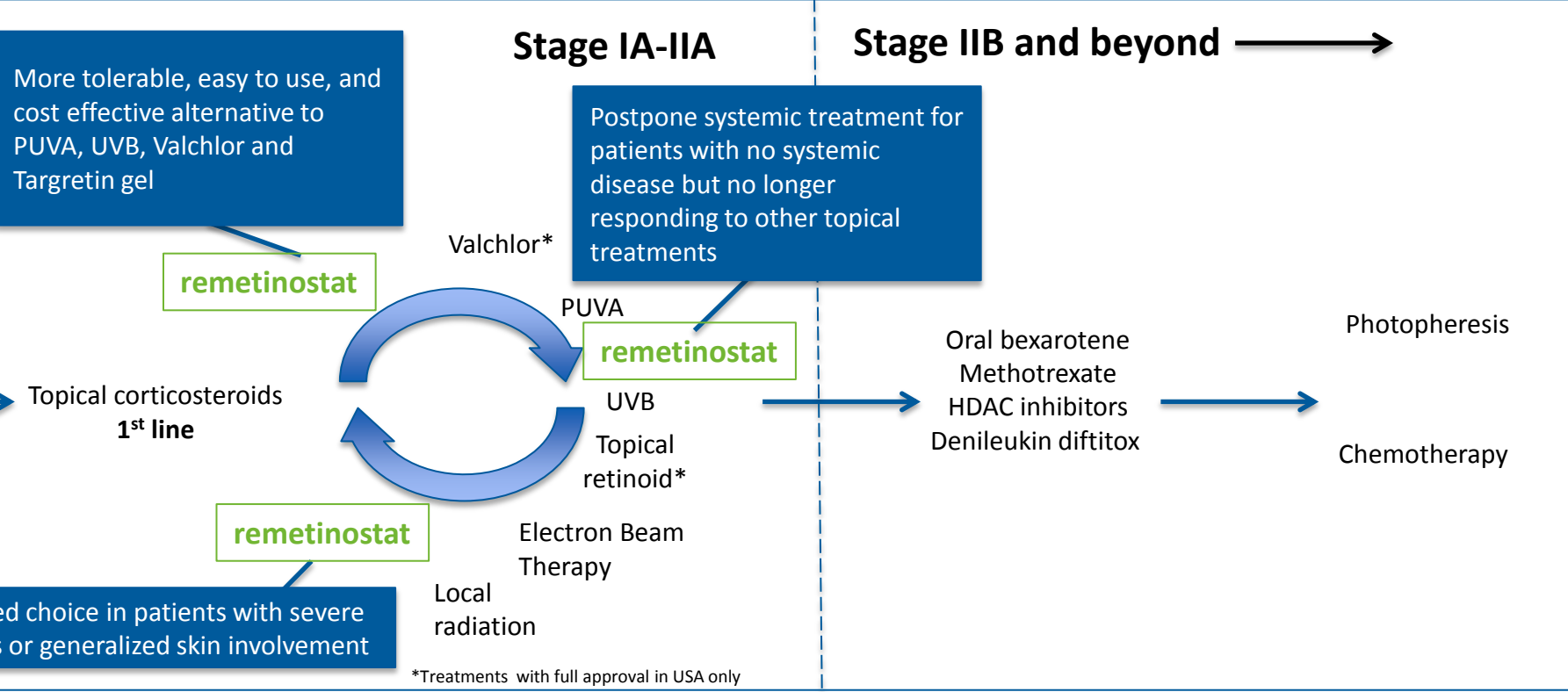


# Remetinostat: an important additional CTCL option for dermatologists

## Key unmet needs

- Efficacy on lesions not responding to current therapy
- Reduction of clinically significant pruritus
- Tolerability, especially for continuous and extended treatment over large lesion areas and for surrounding normal skin

## Remetinostat Positioning



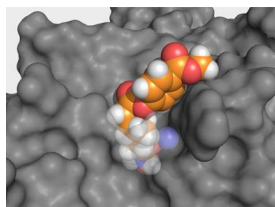
**Remetinostat can capture significant market share based on its clinical profile balancing efficacy, safety and tolerability. This profile is also expected to result in significant QoL benefits for patients.**

Sources: Medivir market research, Phase I and Phase II retinostat clinical trial data

## Remetinostat CTCL clinical trial results promising to date with Phase III program expected to start in 2H 2017



remetinostat



### Clinical Stage

Phase II

### Indication

Early stage cutaneous t-cell lymphoma (CTCL, an orphan hematologic cancer)

### Mechanism

Skin-directed histone deacetylase (HDAC) inhibitor

### Interim phase II data in highly treatment-experienced population demonstrate efficacy profile appropriate for early stage CTCL

- Open-label Phase II design facilitated Medivir's review of the trial data
- Complemented by extensive discussions of the data with CTCL physicians

### Safety and tolerability profile consistent with the skin-specific activity of the drug

- No AEs typically associated with systemic HDAC inhibitors were observed



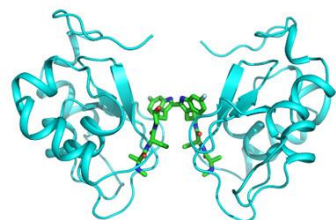
- Planning underway for Phase III start in 2H 2017 with potential for launch in 2021
- Phase III program expected to be of modest size and cost

**As a topical, skin-specific HDAC inhibitor, remetinostat has the potential to be efficacious and have an improved safety profile considering other available treatments**

# Combination trial with Keytruda designed to demonstrate enhanced efficacy of PD-1 inhibitors with birinapant across multiple solid tumor types



## birinapant



### Clinical Stage

Phase I

### Indication

Various solid tumors  
(combination with Keytruda)



### Mechanism

Bivalent, second mitochondrial activator of caspases (SMAC) mimetic, an inhibitor of apoptosis proteins (IAP) inhibitor

## Immuno-oncology market dynamics

- **Keytruda: a key part of the immuno-oncology revolution that's transforming care for cancer patients**
  - Approvals in melanoma, NSCLC and HNSCC
- **PD-1 inhibitor revenues now \$3.2B annually<sup>(1)</sup> and growing with additional treatments in late-stage trials**
- **Despite immunotherapy breakthroughs, significant unmet need remains**
  - While some patients derive enormous benefits from the use of a PD-1 antagonist, the benefits can be limited in many patients
  - Identification of combination regimens to enhance the proportion of patients benefitting from IO therapy is a major trend in cancer R&D

## Birinapant benefits

**Birinapant expected to enhance efficacy of treatment in combination with immuno-oncology drugs**

- Enhancement of T-cell and NK-cell function
- Restoration of immune-cell mediated apoptosis

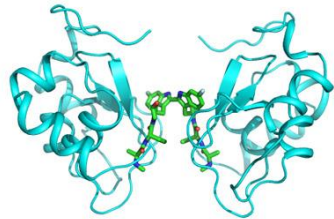
### Collaboration with Merck

- Keytruda provided at no cost
- Joint Development Committee to oversee the study

(1) Sources: Merck and Bristol-Myers Squibb financial reports.

# Birinapant targets a key unmet medical need in high-grade serous carcinoma

## birinapant



### Clinical Stage

Phase II

### Indication

High-grade serous carcinomas (including ovarian cancer)

UCLA

### Mechanism

Bivalent, second mitochondrial activator of caspases (SMAC) mimetic, an inhibitor of apoptosis proteins (IAP) inhibitor

## Serous carcinoma market dynamics

**High-grade serous carcinomas: Group of cancers believed to be derived from cells from the fallopian tube that may present as ovarian, endometrial, tubal or peritoneal cancer**

- HGSC is ~70% of ovarian carcinoma, and ~90% of advanced (stage III/IV) ovarian carcinomas
- Treatment with platinum drugs is standard of care, but most relapse within 6-18 months
- There are few options for patients who relapse with chemotherapy remaining the standard of care even for platinum-resistant carcinomas

**Ovarian cancer market size overall is US\$840M <sup>(1)</sup>**

## Birinapant benefits

**Platinum-resistant HGSC cells are highly susceptible to birinapant in ~50% of patients**

- Tumour-initiating subset of cells resistant to platinum in HGSCs identified by UCLA researchers <sup>(2)</sup>
- Bioassay available to enable patient selection

**UCLA investigator-initiated Phase I/II study planned**

- Combination of birinapant with platinum-based chemotherapy in patients with newly diagnosed or recurrent HGSCs
- Strong scientific rationale and highly motivated clinical investigators
- **Medivir to provide birinapant and potentially some financial support, with full rights to generated data**

(1) Source: DR Decision Resources LLC; (2) DM Janzen et al., Nature Commun. (2015) 6:7956

# Transaction structure weighted toward milestones and royalties while providing a reasonable upfront payment



## Financial Terms

**Upfront:** USD 12m (to be paid from existing cash at closing)

**Remetinostat:**

- Development milestones through regulatory filings of up to USD 20m
- Regulatory approval milestones of up to USD 45m
- Tiered royalties capped at an aggregate of 13%
- Additional commercialization milestones of up to USD 31m, primarily based on substantial sales achievement levels

**Birinapant:**

- Development milestones and research support of up to USD 20m
- Tiered royalties capped at an aggregate of 10%
- Additional commercialization milestones of up to USD 110m, primarily based on substantial sales achievement levels

## Timing and closing conditions

**Closing expected by year-end 2016**

- Tetralogic noteholder consent and shareholder approval required
- Confirmation by Merck/MSD of Keytruda agreement transfer to Medivir required
- Other standard closing requirements

### Transaction delivers high return potential with targeted and de-risked investments

- Significant market opportunities for both products
- Back-end loaded transaction structure with payments upon success
- Mid and late-stage trials commencing 2017 with modest expected cost
- Diversifies against risk in any particular Medivir project with a portfolio approach to the pipeline



## Future communication plans

**Transaction closing expected by year-end 2016**

**Following closing, Medivir expects to provide additional detail on the entire pro forma R&D portfolio, including**

- development plans and timelines
- expected financial requirements for future development



## Right Transaction at the Right Time for the Right Reasons

- ✓ Portfolio of clinical stage programs in oncology that fit with Medivir platform technologies
- ✓ Focused on areas of high unmet medical need and meaningful revenue potential
- ✓ Transforms R&D pipeline enabling a stronger separated business
- ✓ Positioned for sustainable value creation with expected news flow from multiple programs







# Q&A



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

**Ticker: MVIR**

**Exchange: OMX / NASDAQ**

For more information please contact

Ola Burmark, CFO

([ola.burmark@medivir.com](mailto:ola.burmark@medivir.com))

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