

**KURZPROTOKOLL**  
**CHDM201X2101**

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| <b>Öffentlicher Titel</b>   | Phase I Studie zu HDM201 bei soliden und hämatologischen Tumoren mit TP53wt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Wissenschaftl. Titel</b> | A phase I, open label, multicenter, dose-escalation study of oral HDM201 in adult patients with advanced solid and hematological tumors characterized by wild-type TP53                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Kurztitel</b>            | CHDM201X2101                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Studienart</b>           | multizentrisch, prospektiv, mehrarmig                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Studienphase</b>         | Phase I                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Erkrankung</b>           | Blut: Akute lymphatische Leukämie (ALL): Rezidiert/refraktär<br>Blut: Myeloische Neoplasien/Dysplasien: Myelodysplastische Syndrome (MDS)<br>Muskeln/Bewegungsapparat: Knochenkrebs (Sarkome): sonstige Therapiestudien<br>Drüsen/Hormone/Stoffwechsel: Neuroendokrine Tumoren: sonstige Therapiestudien<br>Geschlechtsorgane: Brustkrebs: sonstige Therapiestudien<br>Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: sonstige Therapiestudien<br>Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: sonstige Therapiestudien<br>Haut: Hautkrebs: sonstige Therapiestudien<br>Kopf-Hals: Kopf-Hals-Tumoren: sonstige Therapiestudien<br>Lunge: Lungenkrebs: sonstige Therapiestudien<br>Nervensystem: Gliome: sonstige Therapiestudien<br>Niere/Harnwege: Harnblasenkrebs: sonstige Therapiestudien<br>Niere/Harnwege: Nierenzellkrebs: sonstige Therapiestudien<br>Verdauung: Analkrebs: sonstige Therapiestudien<br>Verdauung: Gastrointestinale Stromatumoren (GIST): sonstige Therapiestudien<br>Verdauung: Gallengangs-/Gallenblasenkrebs (maligne biliäre Tumoren): sonstige Therapiestudien<br>Verdauung: Darmkrebs (Kolorektales Karzinom): sonstige Therapiestudien<br>Verdauung: Leberkrebs (Hepatozelluläres Karzinom): sonstige Therapiestudien<br>Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): sonstige Therapiestudien<br>Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): sonstige Therapiestudien<br>Blut: Akute myeloische Leukämie (AML): Rezidiert/refraktär<br>Weichteile: Sarkome: sonstige Therapiestudien |
| <b>Einschlusskriterien</b>  | <ul style="list-style-type: none"><li>- Patient with a TP53wt locally advanced or metastatic solid malignancy and with measurable or non-measurable (but evaluable) disease as determined by RECIST 1.1 criteria.</li><li>- Patients with the TP53wt hematological tumors (AML, ALL, HR-MDS) who have failed prior therapies or who are considered inappropriate candidates for standard induction therapy.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Ausschlusskriterien</b>  | <ul style="list-style-type: none"><li>- Prior treatment with compounds with the same mode of action</li><li>- Subjects with significant or uncontrolled cardiovascular disease</li><li>- History of thromboembolic or cerebrovascular events within the last 6 months, including transient ischemic attack, cerebrovascular accident, deep vein thrombosis, or pulmonary embolism</li><li>- Previous and concomitant therapy that precludes enrollment, as defined in the protocol</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

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- Known Human Immunodeficiency Virus (HIV) infection and/or active Hepatitis B or Hepatitis C infection
- Patients who have undergone major surgery within the 2 weeks prior to starting study treatment or who have not fully recovered from previous surgery
- Women of child-bearing potential, unless they are using highly effective methods of contraception during dosing and for 2 weeks after study drug discontinuation
- Pregnant or nursing women

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|--------------------------------------------------|----------------------------------------------------------|
| <b>Alter</b>                                     | 18 Jahre und älter                                       |
| <b>Molekularer Marker</b>                        | TP53 wt                                                  |
| <b>Fallzahl</b>                                  | 164                                                      |
| <b>Sponsor</b>                                   | Novartis Pharma                                          |
| <b>Förderer</b>                                  | Novartis Pharma                                          |
| <b>Registrierung in anderen Studienregistern</b> | EudraCT 2013-003521-28<br>ClinicalTrials.gov NCT02143635 |