Studienergebnisse

Savolitinib (ORPATHYS), 100 mg, Filmtabletten

Swissmedic Zulassungsnummer: 70151
Swissmedic Zulassungsdatum: 13.02.2026

Zualssungsstudien

SAVANNAH (D5084C00007)
A Phase II Study Assessing the Efficacy of Osimertinib in Combination With Savolitinib in Patients With EGFRm+ and MET+, Locally Advanced or Metastatic Non Small Cell Lung Cancer Who Have Progressed Following Treatment With Osimertinib.

- EudraCT Nummer: 2018-003012-51
- ClinicalTrials.gov ID: https://www.clinicaltrials.gov/study/NCT03778229

Calquence, Filmtabletten, 100 mg

Swissmedic Zulassungsnummer: 68817
Swissmedic Zulassungsdatum: 07.10.2025

Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung.

Indikationserweiterung:

A Randomized, Multicenter, Open-Label, Phase 3 Study to Compare the Efficacy and Safety of Acalabrutinib (ACP-196) in Combination with Venetoclax with and without Obinutuzumab Compared to Investigator's Choice of Chemoimmunotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukemia Without del(17p) or TP53 Mutation (AMPLIFY)

- EudraCT Number: 2018-002443-28
- ClinicalTrials.gov ID: NCT03836261
- https://www.clinicaltrials.gov/study/NCT03836261?term=2018-002443-28&rank=1

Calquence, Filmtabletten, 100 mg

Swissmedic Zulassungsnummer: 68817
Swissmedic Zulassungsdatum: 06.05.2025

Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung.

Indikationserweiterung:

A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study of Bendamustine and Rituximab (BR) Alone Versus in Combination with Acalabrutinib (ACP-196) in Subjects with Previously Untreated Mantle Cell Lymphoma (ECHO)

- EudraCT Number: 2015-005220-26
- ClinicalTrials.gov ID: NCT02972840
- Study Details | A Study of BR Alone Versus in Combination With Acalabrutinib in Subjects With Previously Untreated MCL | ClinicalTrials.gov

Calquence, Filmtabletten, 100 mg

Swissmedic Zulassungsnummer: 68817
Swissmedic Zulassungsdatum: 07.03.2025

Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung.

Indikationserweiterung:

An Open-label, Phase 2 Study of ACP-196 in Subjects with Mantle Cell Lymphoma

- EudraCT Number 2014-002117-28
- ClinicalTrials.gov ID: NCT02213926
- Study Details | An Open-label, Phase 2 Study of ACP-196 (Acalabrutinib) in Subjects With Mantle Cell Lymphoma | ClinicalTrials.gov

Wainzua (Eplontersen), 45 mg/0.8 ml, Injektionslösung im Fertigpen (Injektion) zur subkutanen Anwendung

Swiss marketing authorization number: 69332
Date of Swiss marketing authorization: 14.02.2025

Zulassungsstudien

ION-682884-CS3
NEURO-TTRansform: A Study to Evaluate the Efficacy and Safety of Eplontersen (Formerly Known as ION-682884, IONIS-TTR-LRx and AKCEA-TTR-LRx) in Participants With Hereditary Transthyretin-Mediated Amyloid Polyneuropathy

- EudraCT Nummer: 2019-001698-10
- Clinical Trials gov ID: NCT04136184
- ClinicalTrials.gov: https://www.clinicaltrials.gov/study/NCT04136184?cond=Polyneuropathy&term=eplontersen&rank=2

Capivasertib (Truqap), 160 mg und 200 mg, Filmtabletten

Swissmedic Zulassungsnummer: 69300
Swissmedic Zulassungsdatum: 19.03.2024

Zulassungsstudien

CAPItello291 (D3615C00001)
A Phase III Double-blind Randomised Study Assessing the Efficacy and Safety of Capivasertib + Fulvestrant Versus Placebo + Fulvestrant as Treatment for Locally Advanced (Inoperable) or Metastatic Hormone Receptor Positive, Human Epidermal Growth Factor Receptor 2 Negative (HR+/HER2−) Breast Cancer Following Recurrence or Progression On or After Treatment with an Aromatase Inhibitor

- EudraCT Nummer: 2019-003629-78
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT04305496

Tremelimumab (Imjudo), Konzentrat zur Herstellung einer Infusionslösung, 20 mg/ml in einer Einzeldosis-Durchstechflasche zur intravenösen Verabreichung

Swissmedic Zulassungsnummer: 68706
Swissmedic Zulassungsdatum: 13.09.2023

Zulassungsstudien

HIMALAYA
A Randomized, Open-label, Multi-center Phase III Study of Durvalumab and Tremelimumab as First-line Treatment in Patients With Advanced Hepatocellular Carcinoma

- EudraCT Nummer: 2016-005126-11
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT03298451

Anifrolumab (Saphnelo), 150 mg/ml in Einzeldosis-Durchstechflasche zur intravenösen Anwendung, Konzentrat zur Herstellung einer Infusionslösung (steriles Konzentrat)

Swissmedic Zulassungsnummer: 68512
Swissmedic Zulassungsdatum: 31.08.2022

Zulassungsstudien

D3461C00004
Efficacy and Safety of Anifrolumab Compared to Placebo in Adult Subjects With Active Systemic Lupus Erythematosus

- EudraCT Nummer: 2014-004632-19
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT02446899

D3461C00005
Efficacy and Safety of Two Doses of Anifrolumab Compared to Placebo in Adult Subjects With Active Systemic Lupus Erythematosus

- EudraCT Nummer: 2014-004633-96
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT02446912

CD-IA-MEDI-546-1013
A Study of the Efficacy and Safety of MEDI-546 in Systemic Lupus Erythematosus

- EudraCT Nummer: 2011-004296-36
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT01438489

Tezepelumab (Tezspire), 210 mg / 1.91 ml, Injektionslösung in Fertigspritze (Injektion) zur subkutanen Anwendung

Swissmedic Zulassungsnummer: 68454
Swissmedic Zulassungsdatum: 13.06.2022

Zulassungsstudien

CD-RI-MEDI9929-1146
Study to Evaluate the Efficacy and Safety of MEDI9929 (AMG 157) in Adult Subjects With Inadequately Controlled, Severe Asthma (PATHWAY)

- EudraCT Nummer: 2013-003269-33
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT02054130

D5180C00007
Study to Evaluate Tezepelumab in Adults & Adolescents With Severe Uncontrolled Asthma (NAVIGATOR)

- EudraCT Nummer: 2017-003078-15
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT03347279

D5180C00009
Study to Evaluate the Efficacy and Safety of Tezepelumab in Reducing Oral Corticosteroid Use in Adults With Oral Corticosteroid Dependent Asthma (SOURCE)

- EudraCT Nummer: 2017-003079-69
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT03406078

D5180C00018
Extension Study to Evaluate the Safety and Tolerability of Tezepelumab in Adults and Adolescents With Severe, Uncontrolled Asthma (DESTINATION)

- EudraCT Nummer: 2018-002501-53
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT03706079

D5242C00001
Efficacy and Safety of Tezepelumab in Participants With Severe Chronic Rhinosinusitis With Nasal Polyposis (WAYPOINT)

- EudraCT Nummer: 2020-003062-39
- ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT04851964

Andexanet alfa (Ondexxya), 200 mg, Pulver zur Herstellung einer Infusionslösung

Swissmedic Zulassungsnummer: 67759
Swissmedic Zulassungsdatum: 02.12.2020

Zulassungsstudien

14-503
A Phase 3 Randomized, Double-Blind, Placebo-controlled Study in Older Subjects to Assess Safety and the Reversal of Apixaban Anticoagulation With Intravenously Administered Andexanet Alfa

- ClinicalTrials.gov: https://www.clinicaltrials.gov/study/NCT02207725

14-504
A Phase 3 Randomized, Double-blind, Placebo-controlled Study in Older Subjects to Assess Safety and the Reversal of Rivaroxaban Anticoagulation With Intravenously Administered Andexanet Alpha

- ClinicalTrials.gov: https://www.clinicaltrials.gov/study/NCT02220725

14-505
Prospective, Open-Label Study of Andexanet Alfa in Patients Receiving a Factor Xa Inhibitor Who Have Acute Major Bleeding (ANNEXA-4)

- EudraCT Nummer: 2015-001785-26
- ClinicalTrials.gov: https://www.clinicaltrials.gov/study/NCT02329327

16-508
A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetics/Pharmacodynamics of Andexanet Alfa Administered to Healthy Japanese and Caucasian Subjects

- ClinicalTrials.gov: https://www.clinicaltrials.gov/study/NCT03310021

16-512
A Phase 1 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Second Generation Andexanet Alfa Administered to Healthy Subjects

- ClinicalTrials.gov: https://www.clinicaltrials.gov/study/NCT03083704

18-513
A Randomized Clinical Trial of Andexanet Alfa in Acute Intracranial Hemorrhage in Patients Receiving an Oral Factor Xa Inhibitor

- EudraCT Nummer: 2018-002620-17
- ClinicalTrials.gov: https://www.clinicaltrials.gov/study/NCT03661528