



Chronic obstructive pulmonary disease (COPD)

Clinical benefit of bronchodilation
POET
 SPIRIVA® vs. salmeterol, 7,350 patients

Maximal bronchodilation
OCTANE
 SPIRIVA® + salmeterol vs. seretide/adair, 344 patients

SPIRIVA® in maintenance treatment naive patients
MAINTANANCE NAIVE
 SPIRIVA® vs. placebo, 436 patients

Effect of 2-years treatment with SPIRIVA® on exercise endurance time
EXACTT
 SPIRIVA® vs. placebo, 519 patients

Comparison of exacerbation efficacy and safety
TIOSPIR
 SPIRIVA® RespiMat® vs. HandiHaler®, 18,800 patients

Reduction in exacerbation rate with SPIRIVA® RESPIMAT®
205.372
 SPIRIVA® vs. placebo, 3,991 patients

Improvement of exercise capacity in early COPD
205.440 (Exercise in early COPD)
 SPIRIVA® vs. placebo, 124 patients

Hypertension

TWYNSTA® in severe hypertension
TEAMSTA (1235.20)
 Telmisartan/amlopidine (80/10 mg) vs. telmisartan 80 mg and amlodipine 10 mg, 760 patients

TWYNSTA® in hypertensive patients with diabetes
TEAMSTA (1235.21)
 Telmisartan/amlopidine (80/10 mg) vs. amlodipine 10 mg, 520 patients

Diabetes

BI 1356 in combination with pioglitazone
1218.15
 Linagliptin (BI 1356) + pioglitazone vs. placebo + pioglitazone, 375 patients

BI 1356 in monotherapy
1218.16
 Linagliptin (BI 1356) vs. placebo in monotherapy, 500 patients

BI 1356 in combination with metformin
1218.17
 Linagliptin (BI 1356) vs. placebo in combination with metformin, 700 patients

BI 1356 in combination with metformin + SU
1218.18
 Linagliptin (BI 1356) vs. placebo in combination with metformin + SU, 1,000 patients

BI 1356 in combination with metformin
1218.20
 Linagliptin (BI 1356) vs. SU in combination with metformin, 1,500 patients

BI 1356 in patients with type 2 diabetes and severe renal impairment
1218.43
 Linagliptin (BI 1356) vs. placebo, 130 patients

BI 10773 monotherapy
1245.9
 BI 10773 vs. placebo, OL metformin, 408 patients

BI 10773 in combination with metformin
1245.10
 BI 10773 vs. placebo in combination with metformin, OL sitagliptin, 495 patients

Acute VTE treatment; secondary VTE prevention

Secondary prevention of venous thromboembolism
RESONATE®
 PRADAXA® vs. placebo, 1,800 patients

Treatment of acute venous thromboembolism
RECOVER®
RECOVER® II
 PRADAXA® vs. warfarin, 5,000 patients

Secondary prevention of venous thromboembolism
REMEDY®
 PRADAXA® vs. warfarin, 2,000 patients

Restless legs syndrome (RLS)

6 months pramipexole study in primary RLS
248.629
 SIFROL®/MIRAPEX® vs. placebo, 331 patients

Hepatitis C

BI 201335 in treatment naive HCV patients
SILEN-C1
 BI 201335 + pegIFN/ribavirin vs. placebo + pegIFN/ribavirin, 430 patients

Shorter treatment duration in treatment naive HCV patients
SILEN-C3
 BI 201335 + pegIFN/ribavirin vs. placebo + pegIFN/ribavirin, 140 patients

BI 201335 in treatment experienced HCV patients
SILEN-C2
 BI 201335 + pegIFN/ribavirin vs. placebo + pegIFN/ribavirin, 390 patients

Oncology

BIBW 2992 in patients with progressed non-small cell lung cancer (NSCLC)
LUX-Lung 1
 BIBW 2992 vs. placebo (phase III/III) after erlotinib or gefitinib, 560 patients

BIBW 2992 in NSCLC patients with EGF receptor mutations (NSCLC)
LUX-Lung 2
 BIBW 2992 (phase II), 120 patients

BIBW 2992 as first line treatment in NSCLC patients with EGF receptor mutations
LUX-Lung 3
 BIBW 2992 vs. cisplatin + pemetrexed (phase III), 330 patients

BIBW 2992 in NSCLC patients progressing after conventional EGFR TKI (Japan)
LUX-Lung 4
 BIBW 2992 (phase I/II), 72 patients

BIBW 2992 compared to standard first-line chemotherapy NSCLC patients with EGF receptor mutations (China)
LUX-Lung 6
 BIBW 2992 vs. cisplatin + gemcitabine (phase III), 330 patients

BIBW 2992 alone and in combination with paclitaxel in NSCLC patients progressing after chemotherapy and EGFR TKI
LUX-Lung 5
 BIBW 2992 + paclitaxel vs. investigator's choice chemotherapy (phase III), 900 patients

BIBF 1120 in combination with docetaxel in patients with advanced NSCLC
LUME-Lung 1
 BIBF 1120 + docetaxel vs. placebo + docetaxel (phase III), 1,300 patients

BIBF 1120 in combination with pemetrexed in patients with advanced NSCLC
LUME-Lung 2
 BIBF 1120 + pemetrexed vs. placebo + pemetrexed (phase III), 1,300 patients

BI 6727 alone or in combination with pemetrexed in NSCLC
1230.5
 BI 6727 + pemetrexed vs. pemetrexed (phase II), 150 patients

BI 6727 as monotherapy or in combination with cytarabine in patients with acute myeloid leukaemia (AML)
1230.4
 BI 6727 + cytarabine vs. cytarabine (phase I/II), 140 patients

Parkinson's disease (PD)

Early vs. delayed start study in PD
PROUD
 SIFROL®/MIRAPEX® vs. placebo, 535 patients

Pramipexole ER in advanced PD
248.525
 Pramipexole ER vs. pramipexole IR vs. placebo, 518 patients

Pramipexole ER in early PD
248.524
 Pramipexole ER vs. pramipexole IR vs. placebo, 539 patients

Pramipexole ER switch trial
248.636
 Pramipexole ER vs. pramipexole IR, 156 patients

Stroke

AGGRENOX® within 24 hours of an acute ischaemic stroke
EARLY
 Early AGGRENOX® within 24h of stroke symptoms vs. late AGGRENOX® after 7 days of stroke, 543 patients

Asian observational study in acute ischaemic stroke
SITS-New
 ACTILYSE®, no comparator, 6,483 patients

Pulmonary embolism

Thrombolysis in acute pulmonary embolism
PEITHO
 METALYSE® vs. placebo, 1,000 patients

Idiopathic pulmonary fibrosis

Effect of BIBF 1120 in patients with idiopathic pulmonary fibrosis
TOMORROW
 BIBF 1120 vs. placebo, 500 patients

Acute coronary syndrome

Secondary prevention of cardiac events in patients with ACS
REDEEM
 PRADAXA® vs. placebo in addition to standard dual anti-platelet therapy (ASA + clopidogrel), 1,878 patients

Myocardial infarction

Early fibrinolysis in STEMI patients (3 hours of onset) followed by catheterisation within 6-24 hours or rescue intervention versus primary PCI*
STREAM
 METALYSE® vs. primary PCI*, 2,000 patients

* Percutaneous Coronary Intervention

Deep vein thrombosis (DVT) prevention (knee)

Prevention of venous thromboembolism post total knee replacement
REMOBILIZE®
 PRADAXA® vs. enoxaparin 30 mg BD, 2,610 patients

Prevention of venous thromboembolism post total knee replacement
REMODEL®
 PRADAXA® vs. enoxaparin 40 mg QD, 2,100 patients

Deep vein thrombosis (DVT) prevention (hip)

Prevention of venous thromboembolism post total hip replacement
RENOVATE®
 PRADAXA® vs. enoxaparin, 3,500 patients

Prevention of venous thromboembolism post total hip replacement
RENOVATE® II
 PRADAXA® 220mg QD vs. enoxaparin 40 mg QD, 1,920 patients

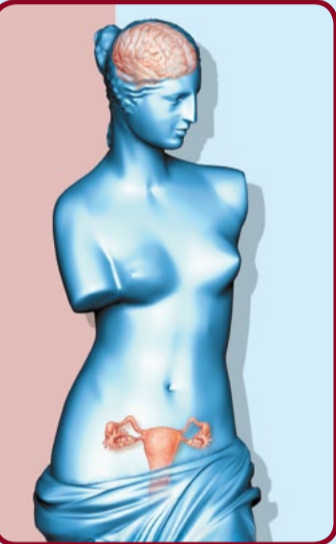
HIV infection

VIRAMUNE® vs. atazanavir/r on a background of tenofovir/emtricitabine
ARTEN
 VIRAMUNE® vs. atazanavir/r plus background, 581 patients

Compare VIRAMUNE® bid with nevirapine XR formulation
VERXVE
 VIRAMUNE® vs. VIRAMUNE® XR plus background, 1,000 patients

Search for genetic markers that might predispose for skin/liver AE
TOXICOGENOMICS
 Case control study, patients with VIRAMUNE® AE vs. patients without AE, 770 patients

Transition from VIRAMUNE® IR to XR formulation
TRANXTION
 VIRAMUNE® transition to XR vs. continuing on IR, 460 patients



Prevention of mother-to-child transmission (MTCT) of HIV

Breastfeeding, Transmission Prevention Strategies
DAIDS Cooperation 1100.1398
 VIRAMUNE® for 6 weeks vs. 6 months, 1,500 mother/child pairs

Hypoactive sexual desire disorder (HSDD)

Efficacy & safety, pivotal I
DAHLIA
 Fibanserin vs. placebo, 1,385 patients

Open-label 6 months safety study for completers of ORCHID
MAGNOLIA
 Fibanserin, 455 patients

Efficacy & safety, pivotal II
VIOLET
 Fibanserin vs. placebo, 880 patients

Efficacy & safety - premenopausal
BEGONIA (511.147)
 Fibanserin vs. placebo, 900 patients

Efficacy & safety, pivotal III
DAISY
 Fibanserin vs. placebo, 1,581 patients

Efficacy & safety, pivotal I - postmenopausal
SNOWDROP (511.130)
 Fibanserin vs. placebo, 900 patients

Randomized withdrawal (48-week sustained efficacy)
ROSE
 Fibanserin vs. placebo, 600 patients

Efficacy & safety, pivotal II - postmenopausal
PLUMERIA (511.156)
 Fibanserin vs. placebo, 900 patients

EU efficacy & safety
ORCHID
 Fibanserin vs. placebo, 945 patients

Open-label one-year safety study for completers of N. American trials
SUNFLOWER
 Fibanserin, 1,723 patients

Open-label 7 months safety study for completers of N. American postmenopausal trials
OLEANDER (511.133)
 Fibanserin, 1,100 patients

Safety study in premenopausal women
511.114
 Fibanserin vs. placebo, 200 patients

Planned patients.

Oncology

BIBW 2992 in HER2-positive patients (after trastuzumab failure)
LUX-Breast 1
 BIBW 2992 + vinorelbine vs. trastuzumab + vinorelbine (phase III), 780 patients

BIBF 1120 in combination with standard chemotherapy in advanced ovarian cancer
LUME-Ovar 1
 BIBF 1120 + carboplatin/paclitaxel vs. placebo + carboplatin/paclitaxel (incl. maintenance, phase III), 1,300 patients

Landmark Trials

UPLIFT®		Chronic obstructive pulmonary disease (COPD)	8,018 patients
RE-LY®		Stroke	18,113 patients
ONTARGET®		Cardiovascular protection	25,620 patients
TRANSCEND®		Cardiovascular protection	5,926 patients
ECASS 3®		Stroke	821 patients
PROFESS®		Stroke	20,332 patients

Clinical Activities at Boehringer Ingelheim in Numbers

During the past decade from 2000 to 2009, Boehringer Ingelheim conducted or sponsored 1,296 studies with 112 substances in 84 countries from all regions of the world.

Study type	Number of Protocols
Phase I	414
Phase II	138
Phase III	169
Phase IV	80
PMS studies	210
Consumer healthcare	42
Other*	35
Co-sponsored studies	208

The studies enrolled approximately 1.15 million patients during this decade, of which nearly 350,000 were in Phase I-IV studies and over 730,000 in PMS studies (post-marketing surveillance). The term 'patient' refers here in a wider sense to patients receiving test medication, comparative medications, placebo, marketed medication, or being healthy volunteers. Detailing these numbers by region and clinical phases reveals a broad geographical distribution with emphasis on North America and West Europe.

Region	I-III	IV	Other	PMS
Africa	5,164	2,687		
America, Latin	8,040	5,660	103	46,500
America, North	71,839	33,665	3,080	32,921
Asia (other)	20,382	13,637		175,826
Australia	3,178	3,110	112	
Europe, West	91,278	37,579	69,307	400,049
Asia (Japan)	12,111	2,105		51,432
Europe, East and Austria	24,616	10,757	384	28,247
Middle East	1,282	860		
Total	237,890	109,860	72,986	734,975

*The category 'Other' includes, for example, compassionate use and methodological studies.