"One moon dispels the darkness,
not thousands of stars"

Chanakya

Vestra Clinics

WE ARE VESTRA

FAMOUS FOR CLINICAL EXCELLENCE

- Specialized in Alzheimer's Disease
- Outstanding Clinical Research
- Committed to Patient Recruitment
- Efficient & Accurate Service

Testimonials – Experience with us

These testimonials from our partners highlight how collaboration with our team enables delivery of exemplary clinical research.

AZTHERAPIES

"I have been very impressed with the quality of data generated by Vestra Clinics under the direction of Dr. Pazdera. As a top enroller, Dr. Pazdera did exactly what he promised when he was recruited to participate in our study. This site is highly recommended and we look forward to working with them in the future."

David Brazier
Vice President, Clinical Operations
AZTherapies Inc.
200 Clarendon St, 17th Floor
Boston, MA 02116

teva

This memo is to confirm the participation of Vestra Clinics in the FOCUS study of Teva Pharmaceuticals Evaluating the Efficacy and Safety of Fremanezumab for the Prophylactic Treatment of Migraine in Patients with Inadequate Response to Prior Preventive Treatments. Principal Investigator was Dr. Ladislav Pazdera.

Dr. Pazdera and his team were the highest enrolling site of the study globally, out of 112 clinical sites. The team successfully screened 43 patients for participation in the study and randomized 31 patients.

A total of 112 sites screened 1028 subjects and enrolled 838 subjects globally. Dr. Pazdera site met all study timeline and was significant contributor to the study.

Melissa Grozinski-Wolff
Director, Global Clinical Project Management
Teva Branded Pharmaceutical
Products R&D, Inc.
41 Moores Road
Frazer, Pennsylvania 19355
USA

AXOVANT
THE POWER OF AN OPEN MIND™

March 6th, 2018

This memo will confirm the participation of Vestra Clinics sro in Axovant's MINDSET study that compared RVT-101 35 mg to placebo in patients with mild to moderate Alzheimer's disease. The Principal Investigator was Dr. Ladislav Pazdera.

Dr. Pazdara and his team were the highest enrolling site of the five sites in the Czech Republic, the 2nd highest enrolling site in the EU, and the 3rd highest enrolling site in the study globally. The team successfully screened 31 patients for participation in the study, and randomized 27 patients. This represented 40% of all patients screened in the Czech Republic, and 47% of all patients randomized in the country. Dr. Pazdera had a very low screen failure rate of only 13%, and all randomized patients completed the trial, compared to a nearly 40% screenfail rate overall.

A total of 177 sites screened 2173 patients and enrolled 1315 patients in 19 countries around the world. Dr. Pazdera's site met all timelines, and was a significant contributor to the study. He was audited by Axovant, and had no critical and no major findings.

Shari Coslett
Vice President Clinical Operations
Axovant Sciences Inc.
11 Times Square, 33rd Floor
New York, NY 10036

BAYER

October 7th, 2021

This memo is to confirm the participation of Vestra Clinics in the PUCCINI study that assess the efficacy and safety of BAY 1817080 in patients with diabetic neuropatic pain. The Principle Investigator was Dr. Ladislav Pazdera.

Dr. Pazdera and his team was the highest enrolling site in the study globally. They successfully screened 19 patients and randomized 15 patients.

Dr. Pazdera´s site met all timelines and was significant contributor to the study.

Jana Koublová
Manager of Monitoring
Bayer s.r.o.
Siemensova 2717/4
155 00 Praha 5

WE ...

...deliver optimal clinical trials solutions, **FAST**.

...**ARE A WORLD LEADER** in patient recruitment, ranking first in global clinical trials.

...offer a comprehensive service from a dedicated and experienced **PROFESSIONAL TEAM**.

...cover a broad **RANGE OF THERAPEUTIC** areas.

...establish **STRONG AND PRODUCTIVE RELATIONSHIPS** with Sponsors and CROs.

World Leader in Patient Recruitment

Our recruitment methods are professionally geared towards the given patient population, so we can aim for much higher enrollment numbers. Hence, we are frequently ranked as the best recruiters.

- **Conducted almost 100 phase II and III RCTs**
- **Enrolled more than 600 patients**

Protocol No	Eudra-CT No	NCT	Diagnosis	Sponsor / Investigator Iniciated	Ph	Active compound	Targeeted Number of Patients	Scree-ned	Rando-mized	Target No Delivered	Special Achievment
Top 3 in the World in Recruitment											
RVT-101-3001	2015-002957-37	NCT02585934	Alzheimer's Disease	**Axovant Sciences Ltd.**	3	intepirdine	20	31	27	135 %	
AZT-001	2015-002147-34	NCT02547818	Alzheimer's Disease	**AZTherapies, Inc.**	3	Ibuprofen/sodium cromoglicate	30	78	31	103 %	Rescue center, first 9 succesfull screened patients in 5 weeks
12936A	2009-011845-24	NCT01019421	Alzheimer's Disease	**H. Lundbeck A/S**	2	idalopirdin	12	31	20	167 %	
14861A	2012-004763-45	NCT01955161	Alzheimer's Disease	**H. Lundbeck A/S**	3	idalopirdin	17	30	20	118 %	First 2 patients randomization / dozed in the World
NSC15001	2015-005263-16	NCT03069014	Alzheimer's Disease	**Frank Longo PharmatrophiX**	2	LM11A-31	8	39	26	325 %	
BIA-2093-311	2009-011135-13	NCT01162460	Epilepsy	**Bial-Portela & Ca, S.A.**	3	eslicarbazepin	10	14	14	140 %	
BIA-2093-311/EXT	2015-001243-36	NCT02484001	Epilepsy	**Bial-Portela & Ca, S.A.**	3	eslicarbazepin	5	5	5	100 %	
093-046	2010-018684-42	NCT01091662	Epilepsy	**Sunovion Pharmaceuticals Inc.**	3	eslicarbazepin	7	21	13	186 %	
093-050	2010-19000-22	NCT00910247	Epilepsy	**Sunovion Pharmaceuticals Inc.**	2	eslicarbazepin	7	10	10	143 %	
GWEP1330 B	2014-002594-11	NCT02365610	Epilepsy	**GW Research Ltd.**	2	cannabidivarin	6	9	6	100 %	First 43 screened patients in 10 weeks
TV48125-CNS-30068	2017-002441-30	NCT03308968	Migraine	**Teva Pharmaceutical Industries, Ltd.**	3	fremanezumab	12	43	31	258 %	
BAY 1817080	2020-002066-14		Neuropathic pain	**Bayer AG**	2	P2X3 antagonist	10	19	15	150 %	The first patient enrolled first in the world
8477-CL-0020	2013-002521-27	NCT02065349	Neuropathic pain	**Astellas Pharma Europe B.V.**	2	quetenza	10	16	13	130 %	
E05-CL-3002	2009-016458-42	NCT01478607	Neuropathic pain	**Astellas Pharma Europe B.V.**	3	Qutenza®	15	29	23	153 %	First patient scree-ned, randomized, dozed, randomiza-tion still ongoing
OF_NEIR_CT1	2019-002632-90	-	Radiculopathy pain	**Biomapas**	3	neiromidine	12	16	16	133 %	
MRZ 60201/SP/3001	2010-023043-15	NCT01392300	Spasticity	**Merz Pharmaceutical GmbH**	3	botulotoxin	25	28	28	112 %	First 28 successful screened patients in 20 weeks
MRZ 60201/SP/3002	2010-024579-23	NCT01464307	Spasticity	**Merz Pharmaceutical GmbH**	3	botulotoxin	20	25	21	105 %	
Top 3 in Europe / Home in Recruitment											
CL2-38093-011	2010-024626-37	-	Alzheimer's Disease	**Servier, Institut de Recherches International**	2	S38093	20	32	15	75 %	
EVP-6124-025	2013-002653-30	NCT01969136	Alzheimer's Disease	**Forum Pharmaceuticals, Inc.**	3	encenicline	8	14	10	125 %	
ALZ-801-201ADBM	2020-000986-17	NCT04693520	Alzheimer's Disease	**Alzheon**	2	tramiprosate / homotaurine	7	25	8	114 %	First patient randomized / first dosed in the World
GWEP1330 A	2014-002594-11	NCT02369471	Epilepsy	**GW Research Ltd.**	2	cannabidivarin	3	2	2	67 %	
GWEP1330 B	2014-002594-11	NCT02365610	Epilepsy	**GW Research Ltd.**	2	cannabidivarin	6	9	6	100 %	
DS5565-A-E309	2013-005161-40	NCT02146430	Pain, fibromyalgia	**Daiichi Sankyo Development Ltd.**	3	mirogabalin	10	19	11	110 %	Fastest enrollment in 6 weeks as a rescue site
AS0006	2015-001894-41	NCT02552212	Pain, spondylarthritis	**UCB BIOSCIENCES GmbH**	3	certolizumab	3	15	5	167 %	
P05664	2009-015161-13	NCT01155479	Parkinson's Disease	**Merck & Co.**	3	preladenant	10	18	14	140 %	
P05664	2009-015161-13	NCT01155479	Parkinson's Disease	**Merck & Co.**	3	preladenant	10	18	14	140 %	Best in Europe in Treatment Naive Patients

The Recruitment Success Story

This leads to robust, powerful, efficient, fast, predictable and accountable delivery that contributes to the completion of clinical trials in a cost-effective and timely manner.

- We carefully **pre-screen the patient population**
- For each clinical trial, **enrollment is launched proactively and simultaneously**, with the momentum sustained until all eligible patients are screened
- The first patient is typically **screened immediately after the initiation visit**
- We engage a **full-time Recruitment and Start-Up Consultant**
- We **maintain the database, network** with >80 cooperating healthcare professionals and institutions, and **educate** physicians, patients and their families as well as developing **marketing** plans
- We conduct **Educational Seminars**, run a proprietary **Memory Clinic**, **Cognitive Rehab Center**, **Epilepsy Clinic** and **Migraine Clinic**
- We **advertise** in newspapers, social media and in radio broadcasts via skilled and successful marketers

Diagnosis	Sponsor	Ph	Targeeted Number of Patients	Randomized	Target No Delivered	Special Achievment
Success Stories						
Alzheimer's Disease	**Alzheon**	2	7	8	114 %	First patient randomized / first dosed in the World
Alzheimer's Disease	**AZTherapies, Inc.**	3	30	31	103 %	Rescue center, first 9 succesfull screened patients in 5 weeks
Neuropathic pain	**Bayer AG**	2	10	15	150 %	The first patient enrolled first in the world
Radiculopathy pain	**Biomapas**	3	12	16	133 %	First patient screened, randomized, dozed, randomization still ongoing
Alzheimer's Disease	**Frank Longo PharmatrophiX**	2	8	26	325 %	First 2 patients randomization / dozed in the World
Parkinson's Disease	**Merck & Co.**	3	10	14	140 %	Best in Europe in Treatment Naive Patients
Spasticity	**Merz Pharmaceutical GmbH**	3	25	28	112 %	First 28 successful screened patients in 20 weeks
Migraine	**Teva Pharmaceutical Industries, Ltd.**	3	12	31	258 %	First 43 screened patients in 10 weeks
Pain, spondylarthritis	**UCB BIOSCIENCES GmbH**	3	3	5	167 %	Fastest enrollment in 6 weeks as a rescue site

Sponsors and CRO Partners in clinical trials

Acadia Pharmaceuticals
Accelsiors
Acorda Therapeutics
Allergan
Amgen
Angelini
Adagio Therapeutics Inc.
Apodemus
Astellas
Avanir Pharmaceuticals
Axovant Sciences
AZTherapies
BenevolentAI Bio
Bial-Portela
Biomapas
Biotie Therapies
Boehringer Ingelheim
Bristol-Myers Squibb
Cerevel Therapeutics
Chiltern International
Cortexyme
Covance
Daiichi Sankyo
EastHORN Clinical Services
EIP Pharma
Eisai Medical Research
Forum Pharmaceuticals
GlaxoSmithKline
GW Research
Laboratorios Lesvi, S.L.
Lundbeck
Heptares Therapeutics
Hoffman La-Roche
ICON Clinical Research
Institut Dr. Schauerte
Iqvia
Janssen-Cilag
Julius Clinical
Linical
Lupin
Merck & Co
Merz Pharmaceutical
Mundipharma Research
Neox Clinical Research
Neurocrine Biosciences
NeuroDerm
Neuroscios
Novartis
Omnicare Clinical Research
NSC Therapeutics
Orion Pharma
PAREXEL
Pfizer
Pharmaceutical Product Development
PharmatrophiX
PRA Health Services
Purdue Pharma
Regeneron Pharmaceuticals Inc
Revance Therapeutics Inc
Scope International
Selecta Biosciences
Servier Institute de Recherches
SK Biopharmaceuticals
Sunovion
Syneos
Teva Pharmaceutical Industries
TFS International
Theravance
Toyama
UCB
VU University
Alzheimer Center Amsterdam
Western General Hospital Edinburgh
Worldwide Clinical Trials

Dedicated Team of Experts

Vestra Clinics has gained over 12 years of clinical research experience since our dedicated research facility opened in 2008. We have a core team of full-time professionals, experienced and focused Investigators, Nurses, Clinical Coordinators, Recruitment / Start-up Specialist, Administrator and two Quality Assurance (QA) specialists.

The owner and CEO of Vestra Clinics, Ladislav Pazdera, MD, FAAN, has acted as the principal investigator in more than 50 industry-sponsored clinical trials and is an established key opinion leader for a number of Sponsors/CROs.

Vestra Clinics has an Expert Advisor, Dr Joris J. de Bie, MBS, PhD, who is also Executive Director for Global Clinical Operations Global Head of Study Management at Chugai Pharmaceutical Co., Ltd, USA. Dr de Bie brings his vast experience in building and leading clinical operations groups to our research facility.

Our Recruitment / Start-Up Consultant drives recruitment via various activities:

Referral partners: identification and follow-up	Sponsor and CRO/CRA communications	Internal team Coordination
Networking, marketing and advertising	**Recruitment Start-Up Consultant**	Patient screening, management and records
Seminads for physicians nurses and specialists	Reports and statistics	Patient/Family education (meeting, seminars)

We pride ourselves in establishing strong, long-lasting and productive relationships with Sponsors and CROs, based on mutual trust and cooperation.

Clinical Trial Benchmarks

Benchmark	Time
IRB Submission ⌄ **Approval**	2 weeks
Median Time to First Consent	1 week
Protocol Review And Monitoring Committee Application Submitted ⌄ **Approval / Open to Enrollment**	2 weeks
Contract Draft Received ⌄ **Contract Executed**	2 weeks
Budget Draft Received ⌄ **Budget Finalized**	2 weeks
Contract Executed ⌄ **Open to Enrollment**	1 week
Open to Enrollment ⌄ **First Patient In**	2 weeks

Delivering Optimal Clinical Research

We provide a high-quality, flexible service to ensure clinical trials are conducted as efficiently as possible.

Preparation and Partnership	**Advance trial planning** via personal, close cooperation with the Sponsor/CRO, allowing efficiency from initiation to completion
	Rapid clinical trial agreement and budget review, avoiding delays in trial initiation
	Identifying experienced investigators: therapeutic area specialists, research enthusiasts and good communicators with the Sponsor/CRO, with accountability for every step of the trial
	Responsible for contract negotiation and reimbursement of investigators and other personnel within the agreed budget
Patient Focus	**Access to a population of 6 thousand preselected and prescreened patients,** enabling excellent recruitment and retention
	Fast monophasic recruitment of large numbers of suitable patients, selected with the utmost care
	Patient-led approach aimed at securing their attention and cooperation by focusing on respect, clear information, comfort, emotional support and continuity for patients and their families
Operational Excellence	**Full accountability** in every part of every clinical trial
	Efficient and timely monitoring for the trial CRA
	No rework due to high compliance to the trial protocol
	Stringent internal processes to ensure data quality, financial management and ethical standards are maintained
	Close monitoring of trial performance to proactively mitigate risk and instigate preventive measures
	Full time recruitment and start up consultant is employed
	Skilled QA personnel are members of the team
Regulatory Compliance	**Strict adherence to regulatory requirements** for clinical trial conduct including ICH-GCP, FDA, EMA, and local regulations
	Facilitating the preparation of regulatory submissions with the Sponsor/CRO
	Recognised as a highly specialised center (third tier level) for the diagnosis and treatment of dementia by the State Institute for Drug Control (SÚKL)

Broad Therapeutic Area Expertise

We can assist with clinical trials in a range of therapeutic areas, specializing in CNS, pain, metabolic and vascular disorders, and gynecology. For example, we have conducted 26 clinical trials in Alzheimer's disease (13 each in phase II and III, respectively).

Cardiovascular disease	Coronary heart disease (angina, myocardial infarction) Stroke prevention
	Postsurgery procedure evaluation: Coronary artery / Limb artery bypass graf, stent
Dementia	Alzheimer's disease w/o Neuropsychiatric Symptoms
	Mild cognitive deficit
	Prodromal/preclinical phases
Metabolic	Diabetes
	Hypercholesterolemia
	Metabolic syndrome
	Osteoporosis
Neurology	Epilepsy
	Parkinson's disease
	Restless leg syndrome
	Spasticity
	Vertigo
Pain	Chronic / back / neuropathic / osteoarthritic pain
	Fibromyalgia
	Migraine
	Pain syndromes
Psychiatry	ADHD
	Anxiety and depressive disorders
	Eating disorders
	PTSD
	Stress-related / somatoform / sleep disorders
Rheumatology	Osteoarthritis
	Rheumatoid arthritis
	Psoriatic arthritis
	Gout

For more information on partnering with us, please get in touch

Vestra Clinics

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European Union - Czechia

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