SYNOPSIS

Name of Sponsor/Company: Farmak International Holding GmbH	Individual Study Table Referring to Part of the Dossier	(For National Authority Use only)
Name of Finished Product: Amizon®	Volume: Page:	
Name of Active Ingredient: Carbabenzpyride		

EudraCT no. (for Europe only)	2010-018564-17
Study Code	FAV00A-IIA
Title of Study	A Phase II, multicenter, multinational, randomized, double-blinded, placebo-controlled dose-finding study to evaluate the efficacy and safety of carbabenzpyride in the treatment of uncomplicated influenza A
Study Design	Prospective, multicenter, multinational, randomized, double-blinded, placebo-controlled dose-finding study in parallel groups (Phase II)
Phase of Development	II
Coordinating Investigator in Austria (Lead Principal Investigator)	Prof. Dr. Heinz Burgmann, MD, Specialist in Internal Medicine; Vienna General Hospital, Medical University of Vienna (Austria)
Coordinating Investigator in Canada (Lead Principal Investigator)	Dr. Giuseppe D'Ignazio, MD, General Practitioner; Doctor's practice, East Hawkesbury (Canada)
Coordinating Investigator in Germany (LKP according to § 40 German Drug Law)	Dr. Christoph Stephan, MD, Specialist in Internal Medicine; Medizinische Klinik II / Infektiologie at Johann Wolfgang Goethe-Universität Frankfurt / Main (Germany)
Principal Investigators	Specialists in internal medicine and general practitioners
Study Centers	Seventeen (17) out of 28 initiated study sites in Germany, 1 out of 3 initiated study sites in Austria and 3 out of 21 initiated study sites in Canada participated (medical practices and clinics) and recruited patients (including screening failures) in the study.
Countries	Austria, Canada and Germany
Publication (Reference)	None
Studied Period	Approximately 3.5 months (clinical part) Date of first enrolment (first patient first visit): 20 JAN 2011 Date of last completed (last patient last visit): 16 MAR 2011 (randomized patient) 13 APR 2011 (screening failure) Date of termination by the sponsor: 15 APR 2011

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Objectives	Primary objective: • To assess the efficacy of an 8-day treatment with carbabenzpyride in adult subjects with influenza A in three different dosages compared to placebo on the basis of the duration of illness in terms of alleviation of symptoms
Objectives (cont.)	Secondary objectives: • To assess the safety of three different doses of carbabenzpyride compared to placebo in subjects with influenza A • To determine the dose with the best benefit / risk ratio for the treatment of influenza A
Study Visits	Four visits plus two follow-up visits: Visit 1: Screening, baseline assessments, randomization and start of double-blinded treatment (Day 1) Visit 2 – Visit 3: Control examinations at Day 3 (±1) and Day 5 (±1) Visit 4: End of treatment one week after Visit 1 (Day 8 + 1) or earlier in case of premature recovery or withdrawal from the study Visit 5: Follow-up two weeks after Visit 1 (Day 15 ±1) or earlier in case of premature recovery or withdrawal from the study (7 ±1 days after Visit 4) Visit 6: Follow-up four weeks after Visit 1 (Day 29 ±2)

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Methodology	Male and female adult outpatients with influenza A (confirmed by rapid influenza diagnostic test) were screened for study participation from January to April 2011 (winter season in the northern hemisphere). The individual study duration was 29 ±2 days, with a total of six visits. A diary was filled in by the patients from study Day 1 to Day 22. There was no run-in period. Two follow-up examinations were performed in all patients at Visit 5 and Visit 6 (study end). At Visit 1 (Day 1) eligible patients who had given their written informed consent were randomized to one of the four parallel treatment groups. Treatment with the blinded study medication (125 mg, 250 mg, 500 mg carbabenzpyride or placebo capsules) started on Day 1 / Visit 1 in the investigator's office. Patients were instructed to continue taking the medication two times daily (b.i.d.) until Day 8, always at the same time of the day (2 capsules in the morning and in the evening). Paracetamol / acetaminophen was provided as rescue medication. The effect of study treatment on influenza A was evaluated by the change in patient's rating scores (home assessment in a patient diary from Day 1 to Day 22) for the seven main influenza symptoms, namely cough, sore throat, nasal symptoms, headache, fatigue, myalgia, sweat and / or chill, and patient's response to treatment compared to baseline (office assessment from each investigator and patient). Additionally, the virus titer and the antibody response (HAI) were determined during the study. The tolerability of study treatment was evaluated based on the frequency and severity of adverse events, ECG, measurement of vital signs (systolic and diastolic blood pressure, pulse rate, body temperature), analyses of blood parameters (safety laboratory), and by patient's and investigator's global assessment of tolerability at treatment end.

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Methodology (continued)

The following efficacy and safety measures were monitored during the study:

12-lead ECG (investigator)……..	Visits 1, 4
Vital signs (blood pressure, pulse rate, body temperature)……..	Visits 1, 2, 3, 4, 5
Safety laboratory tests……...	Visit 1, 4, 5, 6
Urine pregnancy test for females with childbearing potential……	Visit 1, 4
Virological data (virus subtype, virus titer, phenotyping, genotyping and sequencing)……	Visits 1, 2, 3, 4, 5
Antibody response: hemagglutination inhibition (HAI)……..	Visits 1, 3, 4, 5, 6
Influenza symptoms (patient diary, 4-point rating scale)……..	Twice daily until Day 22
Adverse events……	Visits 2, 3, 4, 5, 6
Drug compliance……	Visits 2, 3, 4
Treatment response by both the investigator and the patient (4-point verbal rating scale)…….....	Visits 2, 3, 4, 5
Global assessment of tolerability by both the investigator and the patient (5-point verbal rating scale).....……..	Visit 4

Number of Patients

Planned: 440 patients (110 patients per treatment group)
Analyzed: (see table below)

Data Set	Carbabenzpyride 500 mg		Carbabenzpyride 1,000 mg		Carbabenzpyride 2,000 mg		Placebo		Total	
	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*
Randomized	2	*100.0*	3	*100.0*	2	*100.0*	3	*100.0*	10	*100.0*
SEP	2	*100.0*	3	*100.0*	2	*100.0*	3	*100.0*	10	*100.0*
FAS	2	*100.0*	2	*66.7*	2	*100.0*	2	*66.7*	8	*80.0*

SEP= Safety population, FAS= Full analysis set

Inclusion Diagnosis

Influenza A, for details see inclusion criterion no. 3

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Main Criteria for Inclusion	1. Subject who has given his / her signed declaration of consent and data protection declaration after having been informed about benefits and potential risks of the study, as well as details of the insurance taken out to cover the subjects participating in the study. 2. Male or female outpatient subject from 18 to 65 years of age 3. Diagnosis of influenza A • characterized by the presence of at least one respiratory symptom (cough, sore throat or nasal symptoms) of at least moderate severity • characterized by the presence of at least one constitutional symptom (headache, myalgia, fatigue or sweats and / or chills) of at least moderate severity • characterized by fever ≥ 37.5°C / ≥ 99.5°F (sublingual) measured at the investigator's office • onset of symptoms no longer than 36 hours before randomization; onset of symptoms is defined as appearance of at least one respiratory **and** one constitutional symptom of any severity • positive influenza A rapid antigen test performed with a commercially available test kit on an adequate nasopharyngeal swab
Investigational medicinal products (IMP)	
Test Product 1: - active ingredient: - substance class: - mode of administration: - batch number: - expiry date:	Carbabenzpyride capsules One capsule contained 125 mg carbabenzpyride. cytokines and immunomodulators oral 11010 (blinded batch no. KM040) 04/2011
Test Product 2: - active ingredient: - substance class: - mode of administration: - batch number: - expiry date:	Carbabenzpyride capsules One capsule contained 250 mg carbabenzpyride. cytokines and immunomodulators oral 31010 (blinded batch no. KM040) 04/2011
Test Product 3: - active ingredient: - substance class: - mode of administration: - batch number: - expiry date:	Carbabenzpyride capsules One capsule contained 500 mg carbabenzpyride. cytokines and immunomodulators oral 11010 (blinded batch no. KM040) 04/2011
Reference - active ingredients: - substance class:	Placebo capsules none none

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- mode of administration.	oral	
- batch number:	2P1010 (blinded batch no. KM040)	
- expiry date:	04/2011	

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Dose regimen:	Three active dose groups were tested versus one placebo group from Day 1 (Visit 1) to Day 8 (Visit 4). Patients were randomly (1:1:1:1) assigned to the following four treatment groups: - carbabenzpyride 250 mg b.i.d.: 2 x 2 capsules of 125 mg / day (500 mg total daily dose) - carbabenzpyride 500 mg b.i.d.: 2 x 2 capsules of 250 mg / day (1,000 mg total daily dose) - carbabenzpyride 1,000 mg b.i.d.: 2 x 2 capsules of 500 mg / day (2,000 mg total daily dose) - placebo b.i.d. Depending on the time of visit intake of study medication was b.i.d. or o.d. for Day 1 and o.d. on the day of Visit 4. On Day 1, the 2nd dose was administered only, if at least 6 hours were in-between. The study medication was administered orally with fluid in the morning and evening. First intake of study medication took place in the investigator's office at Visit 1 (Day 1). Using the respective strength of carbabenzpyride it was ensured that each subject received the same number of capsules per day (2 x 2 capsules).
Duration of treatment:	8 (+ 1) days
Rescue Medication - active ingredients: - substance class: - mode of administration:	Paracetamol / acetaminophen tablets One tablet contained 500 mg paracetamol / acetaminophen. non-opioide analgesics oral
Criteria for Evaluation Primary endpoint	The primary endpoint was defined as the time [days] to alleviation of influenza symptoms from Day 1 (Visit 1) to Day 22 comparing different dosages of carbabenzpyride with placebo in the Full Analysis Set (FAS) population. The time [days] to alleviation of symptoms (cough, sore throat, nasal symptoms, headache, fatigue, myalgia, sweat and / or chill) was calculated for a (maximum) observation period of 21 days (Day 1 to Day 22). Alleviation was defined as the start of a 24 ± 3 hour period, in which a symptom was less or equal to mild intensity (i.e. score = 1) and did not increase for at least 24 hours. The analysis of the primary endpoint was based on the subjects' daily diary assessments.

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Criteria for Evaluation Secondary endpoints - Efficacy	1. AUC of all symptoms (sum of scores of all influenza symptoms) calculated from Day 1 to Day 22 as assessed by the subject in the diary 2. Duration of each individual symptom of influenza from Day 1 to Day 22 as assessed by the subject in the diary 3. AUC of each individual symptom of influenza from Day 1 to Day 22 as assessed by the subject in the diary 4. AUC of all symptoms (sum of scores of all influenza symptoms) calculated from Day 1 to Day 22 for two subgroups, either with or without intake of paracetamol / acetaminophen during the course of the study 5. AUC of virus titer per dose group from Visit 1 to Visit 5 6. AUC of antibody response (HAI) per dose group from Visit 1 to Visit 6 7. Efficacy in flu-like illness (i.e. subgroup of subjects with negative confirmatory influenza test) analogous to the analysis of patients with influenza A, provided there is sufficient number of subjects in this subgroup
- Efficacy (continued)	8. Duration of illness (analyzed analogously to the primary endpoint) for the subgroup of subjects with vaccination against influenza for current season and for the subgroup without such a vaccination 9. Incidence of complications of influenza A such as otitis media, bronchitis, rhinosinusitis and / or pneumonia 10. Response to treatment as judged by the investigator and the subject (each separately) from Visit 2 to Visit 5 11. Percentage of subjects who used rescue medication (paracetamol / acetaminophen) with respect to cumulative dose
- Safety and Tolerability	1. Safety and tolerability by means of ECG, vital signs, safety laboratory tests and adverse events 2. Global assessment of tolerability by the investigator and the subject (each separately)
Statistical Methods	<u>Interim analysis</u> An interim analysis was neither planned nor performed in the study. <u>Final analysis</u> The analyses of the primary endpoint and secondary efficacy endpoints were performed using the full analysis set (FAS) which included all randomized patients with influenza A and with at least one documented application of the investigational drug and post-baseline efficacy data regarding the primary endpoint. Patients with delayed exclusion or negative confirmatory influenza test were excluded from the FAS. The analyses of the secondary safety endpoints were performed using the safety evaluable population (SEP) which included all patients randomized with at least one documented intake of the investigational drug and post-treatment safety data. All data were analyzed exploratively by descriptive statistics. Continuously distributed variables were described by mean values. Standard deviation (SD), minimum, median and maximum were used as indices of dispersion. Categorical variables were described in frequency tables as absolute numbers and percentages.

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Summary – Conclusions Efficacy Results	All subsequent descriptions of efficacy in summary reflect the results of 2 patients per treatment group in the FAS population. Therefore, general conclusions cannot not be drawn. For treatment of influenza A characterized by fever ≥ 37.5°C, ≥ 1 respiratory and ≥ 1 constitutional symptom of at least moderate severity present for a maximum of 36 hours, 1,000 mg carbabenzpyride / day was more effective than placebo, lower (500 mg) or higher (2,000 mg) daily doses of carbabenzpyride. The course of disease was comparable between the placebo group and the 500 mg carbabenzpyride group. The group treated with 2,000 mg carbabenzpyride revealed heterogeneous results with respect to disease improvement, sometimes less and sometimes better than placebo or the lowest carbabenzpyride dose group. The severity of seven influenza symptoms improved as demonstrated by time to alleviation of the symptoms, the course of the symptoms displayed by AUC and the rate of cure and symptom improvement.
Efficacy Results (cont.)	Primary endpoint · In the 1,000 mg carbabenzpyride group, the mean time to alleviation of all influenza symptoms (primary endpoint, patient's rating in the diary from Day 1 to Day 22) was considerably shorter (2.4 days) compared to the 500 mg carbabenzpyride group (8.3 days) and the placebo group (7.6 days). The group treated with the highest dose (2,000 mg) of carbabenzpyride showed the longest mean time to alleviation (11.3 days). Secondary endpoints · In comparison to the other treatment groups, the mean AUC of sum of symptom scores was reduced in the 1,000 mg carbabenzpyride group compared to all other treatment groups. The course of sum of symptoms over 22 days was comparable between the placebo and the 500 mg carbabenzpyride group. After daily treatment with 2,000 mg carbabenzpyride, the AUC was lower compared with the 500 mg carbabenzpyride and placebo group, but considerably higher than in the 1,000 mg carbabenzpyride group. · Demonstrated by the mean time to alleviation, treatment with 1,000 mg carbabenzpyride per day showed the best effect on cough, headache, fatigue and myalgia compared to the other treatment groups. For sore throat and sweat and / or chill the best improvement was observed in the 2,000 mg carbabenzpyride group. The longest mean duration of cough, nasal symptoms and fatigue was calculated for the 2,000 mg carbabenzpyride group. The time to alleviation of cough and sore throat was comparable between placebo and the 500 mg carbabenzpyride group. In the 500 mg carbabenzpyride group, the longest duration of myalgia and sweat and / or chill was observed. The mean time to alleviation of nasal symptoms after any active treatment was longer compared to placebo. · Demonstrated by the mean AUCs, treatment with 1,000 mg carbabenzpyride per day showed a better effect on cough, sore throat, nasal symptoms, headache, fatigue and myalgia compared to the other treatment groups. In the 2,000 mg carbabenzpyride group the best improvement for sweat and / or chill was observed by means of AUC as well as for sore throat, headache and myalgia in comparison to the placebo and 500 mg carbabenzpyride group. For cough, nasal symptoms and fatigue the highest AUC was calculated for the 2,000 mg carbabenzpyride group. Except for sore throat, the mean

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	AUCs of individual symptom scores were roughly comparable between the placebo and the 500 mg carbabenzpyride group. · Values for virus titer at baseline (Visit 1) revealed a high variability. Due to missing baseline values in three patients a comparison of baseline values between treatment groups was not reasonable. After Visit 1 virus titer subsequently decreased and was below limit of quantification at latest at Visit 3 in all patients. In one patient in the 1,000 mg carbabenzpyride group, virus titer was slightly increased at Visit 4 (25.000 vp/mL) but below limit of quantification at the visit before and thereafter. · Subtyping of influenza A revealed negative results for all patients and visits with positive values for virus titer. This was most probably due to the fact that the primers used for the validation of the H1 and N1 subtypes were not optimal for the detection of the seasonal influenza virus isolates (winter 2010/2011) based on the fact that the influenza virus can mutate frequently and quickly especially in H and N genes.
Efficacy Results (cont.)	· At baseline (Visit 1), six (6) of the 8 patients in the FAS had an antibody titer against the subtype H1N1 below limit of quantification. Two (2) patients had a titer above limit of quantification at study start. Throughout the study, the antibody titer increased in all patients and reached a maximum value at Visit 5 or Visit 6. The highest mean and geometric mean AUC values for H1N1 antibody titers were observed in the 500 mg carbabenzpyride group followed by the placebo group. These values were considerably lower in the 1,000 mg and 2,000 mg carbabenzpyride group. · In 6 of 8 patients the values for antibody titers against the subtype H3N2 were below limit of quantification throughout the study. One patient had a low antibody titer at Visit 1 only. Just one patient in the 500 mg carbabenzpyride group showed increasing antibody titer with a maximum value at Visit 5 and 6. · In all treatment groups, no deterioration of influenza A symptoms was observed in comparison to Visit 1 (baseline). According to the investigator's judgment, the best response to treatment was seen in the 1,000 mg carbabenzpyride group with an improvement of symptoms from Visit 1 to Visit 4 and a diagnosed cure at Visit 5 for all patients. In 100% of placebo treated patients, symptom improvement in comparison to Visit 1 was assessed by the investigator from Visit 2 to Visit 5. Unchanged symptoms were observed in 50% of the patients from Visit 2 to Visit 3 (500 mg carbabenzpyride group) and to Visit 4 (2,000 mg carbabenzpyride group) before all patients in these treatment groups showed an improvement of influenza symptoms latest at Visit 5. Similar results were obtained for assessment by the patient. · In total, 62.5% of the randomized patients in the FAS used rescue medication (paracetamol / acetaminophen) during the course of the study without differences in the active treatment groups. However, all FAS patients in the placebo group took rescue medication. In consideration of the low number of included patients, the percentage of patients with rescue medication in the active treatment groups did not differ considerably from the placebo group.

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Summary – Conclusions: Safety Results	Taking into account the low number of randomized study patients, oral daily treatment with 500 mg, 1,000 mg or 2,000 mg carbabenzpyride for about 8 days was safe, well tolerated and comparable to placebo treatment regarding the safety profile. Adverse events Throughout the whole study (Visit 2 to Visit 6 / follow-up), 3 AEs occurred in 2 (20.0%) out of 10 treated patients (SEP) all in the 1,000 mg carbabenzpyride group. No AE was reported in the placebo, 500 mg carbabenzpyride or 2,000 mg carbabenzpyride group. Two (66.7%) out of 3 AEs started during the follow-up period. One AE (dry mouth) started during the treatment period. The AEs were of mild (one) to moderate (two) intensity. No AE was severe. Serious or fatal AEs were not reported. One AE (dry mouth / 33.3%) was classified by the investigator as having a probable causal relationship to the study medication. All other AEs were not related to the study medication. The pattern of the 3 reported AEs was classified as single event (pharyngitis / 33.3%), repeated (dry mouth / 33.3%) or continuous (shoulder arthrosis ambilateral / 33.3%). No patient prematurely discontinued study participation due to an AE. At end of study, 2 (66.7%) out of 3 AEs had resolved. Only shoulder arthrosis ambilateral (33.3%) was ongoing (not resolved).
Safety Results (cont.)	Safety laboratory Except for TSH, safety laboratory parameters did not change considerably from baseline (Visit 1) to the end of the treatment (Visit 4) and follow-up visits. Till Visit 4 (end of treatment), mean TSH increased transiently in the active treatment groups; the increase was much more pronounced compared to placebo. There was no dose relationship for increased mean TSH values. Individual TSH values outside normal range for one patient in each active treatment group returned to normal until Visit 5 in the 500 mg and 1,000 mg carbabenzpyride group and until Visit 6 in the 2,000 mg carbabenzpyride group. Increased TSH values were neither above twofold upper limit of normal range nor judged by the investigator to be clinically relevant. The mean values for the thyroid hormones fT3 and fT4 did not change significantly throughout the study and were comparable between all treatment groups. TPO-antibodies were within normal ranges in all patients during this clinical trial. In one patient of the 1,000 mg carbabenzpyride group, three laboratory values (ALAT, ASAT and GGT) were clinically significant outside normal ranges at baseline, end of treatment and the first follow-up visit. The increased hepatic enzymes were classified as “hepatopathy” in medical history and patient was excluded with delay. No change of safety laboratory parameters from baseline was reported as AE. Vital signs Office measurements during Visit 1 to Visit 5 did not show any clinically relevant changes in mean blood pressure (systolic and diastolic), pulse rate or body temperature in any treatment group. A slight decrease of pulse rate compared to baseline was most probably related to influenza related fever at Visit 1.

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	ECG Three patients of the 1,000 mg carbabenzpyride group showed sinus arrhythmia or other individual abnormalities. The abnormal results of the ECG (right bundle branch block and tachycardia) were judged by the investigator as clinically not significant. Sinus arrhythmia was judged as normal. Right bundle branch block (1 patient) and sinus arrhythmia (1 patient) were documented at Visit 1 and Visit 4, tachycardia (1 patient) only at Visit 1. Global assessment of tolerability Bearing in mind the low number of included patients, the frequency of 'very good' or 'good' ratings was comparable between the active treatment groups altogether (85.7%) and the placebo group (100.0%). The difference of 14.3% between these groups was caused by one moderate tolerability, assessed in the 500 mg carbabenzpyride group. In total, tolerability of treatment was judged as 'good' in 60.0% by the patients and 50.0% by the investigators. Tolerability was rated as 'very good' in 30.0% (by patient) and 40.0% (by investigator). No 'poor' or 'very poor' tolerability of investigational treatment was documented.
Treatment compliance	The average treatment compliance was 100.1% (according to IMP count data in the eCRF) with no relevant difference between the four treatment groups.
Conclusion:	The results of this clinical trial with a low number of patients revealed that 1,000 mg carbabenzpyride per day is more effective in relieving the symptoms of influenza A, as compared to placebo as well as lower and higher daily doses of carbabenzpyride. The treatment effect was comparable between the 500 mg carbabenzpyride and placebo group. The results in the 2,000 mg carbabenzpyride group were heterogeneous: Compared to placebo and the lowest carbabenzpyride dose group the time to alleviation was better for some individual symptoms and worse for others. Oral daily treatment with 500 mg, 1,000 mg or 2,000 mg carbabenzpyride for about 8 days was safe, well tolerated and comparable to placebo treatment regarding the safety profile in these 10 study participants. With respect to a transient increase of mean TSH values in all active treatment groups due to the iodide content of carbabenzpyride, special attention should be paid to patient selection and thyroid function monitoring.
Date of the Report:	28 MAR 2012