Name of Company: Pierre Fabre Médicament	**Individual Study Table**	**(For National Authority Use Only)**
Name of finished product: Navelbine® Oral		
Name of active substance *(or ingredient)***:** Vinorelbine		

Title of study:	Oral Vinorelbine and cisplatin with concomitant radiotherapy followed by either consolidation therapy with oral vinorelbine and cisplatin plus Best Supportive Care or Best Supportive Care alone in stage III non-small cell lung cancer (NSCLC): A randomized Phase III study Latest protocol version: Final protocol 16th Dec 2004 Amendment no. 1 of 23rd May 2006 Amendment no. 2 of 23rd May 2006 Amendment no. 3 of 23rd May 2006 Amendment no. 4 of 3rd May 2007 Amendment no. 5 of 1st Oct 2007 Amendment no. 6 of 28th Feb 2008 Amendment no. 10 of 21st Oct 2008 (including amendments no. 7 of 10th Jun 2008, no. 8 of 1st Jul 2008 and no. 9 of 10th Sep 2008) Amendment no. 11 of 21st Aug 2009
Principal Investigators:	– Prof. Dr. med. Rudolf Huber, Medizinisches Klinikum, Pneumologie, Klinikum der LMU, München – Prof. Dr. med. Michael Flentje, Strahlentherapie der Universität Würzburg, Würzburg – Prof. Dr. med. Rainer Fietkau, Universitätsklinikum Rostock, Klinik und Poliklinik für Strahlentherapie, Rostock ***(until end of 2007)***; Strahlenklinik, Erlangen ***(since beginning of 2008)***
Investigators:	– Dr. med. Guido Hildebrandt, Klinik und Poliklinik für Radiotherapie und Radioonkologie, Leipzig ***(until mid of 2009)***; Universitätsklinikum Rostock, Klinik und Poliklinik für Strahlentherapie, Rostock ***(since end of 2009)*** – Dr. med. Frank Heinemann, Krankenhaus Donaustauf, Pneumologie, Donaustauf – Prof. Dr. med. Oliver Kölbl, Universität Regensburg, Strahlentherapie, Regensburg – Prof. Petra Feyer, Vivantes Klinikum Neukölln, Klinik für Strahlentherapie, Berlin – Dr. med. Henry Simon, Paracelsus Klinik Ruit, Ostfildern – Dr. Michael van Kampen, Krankenhaus Nordwest, Frankfurt – Prof. F. Griesinger, Georg August Universität Göttingen, Hämatologie und Onkologie, Göttingen ***(until mid of 2007)*** Pius Hospital, Strahlentherapie & internistische Onkologie, Oldenburg ***(since mid of 2007)*** – Dr. med. Andreas Jakob, Klinikum Offenburg, Med. Klinik II, Offenburg – Dr. med. Klaus Pfändner, Leopoldina Krankenhaus / Strahlentherapie, Schweinfurt – PD Dr. med. G. Becker, Klinikum am Eichert, Radioonkologie, Göppingen – Dr. med. Jochen Willner, Klinikum Bayreuth, Bayreuth – Dr. med. Jens Kollmeier, Helios Klinikum, Berlin – Prof. Dr. med. Wolfgang Hoffmann, Städtisches Klinikum Braunschweig, Radioonkologie & Strahlentherapie, Braunschweig – Prof. Wolfgang Hinkelbein, Charité Campus Benjamin Franklin, Klinik und Hochschulambulanz für Radioonkologie und Strahlentherapie, Berlin – Prof. Bernd Kober, Klinikum Darmstadt, Radioonkologie/Strahlentherapie, Darmstadt – Prof. Frederik Wenz, Klinikum Mannheim gGmbH, Strahlentherapie, Mannheim – Dr. med. Ludwig Fischer von Weikersthal, Klinikum St. Marien, Amberg – Prof. Dr. med. Stefan Andreas, Lungenfachklinik Immenhausen, Immenhausen/Kassel

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	– Dr. med. Ulf Sibelius, Medizinische Klinik V – Internistische Onkologie und Allergologie, Gießen – Dr. Nicolas Dickgreber, Medizinische Hochschule Hannover, Zentrum für Innere Medizin, Abt. Pneumologie, Hannover – Prof. Dr. med. Christian Rübe, Universitätsklinik des Saarlandes, Strahlentherapie, Homburg – Dr. med. Sylvia Gütz / Dr. med. Angelika Friedrichs, Klinikum St. Georg gGmbH, Robert-Koch-Klinik, 04207 Leipzig – PD Dr. Susanne Staar, Klinikum Bremen-Mitte, Strahelntherapie, Bremen – Dr. Walburga Engel-Riedel, Kliniken der Stadt Köln gGmbH, Krankenhaus Merheim, Lungenklinik, 51109 Köln – Dr. med. Alexander D. Boicev, Klinik für Strahlentherapie und Radioonkologie, Heinrich-Braun-Krankenhaus Zwickau, Zwickau – Dr. med. Maria Degen, Pneumologische Klinik, Greifenstein – Dr. Michael Allgäuer, Krankenhaus der Barmherzigen Brüder, Regensburg – Prof. Dr. med. Nikolaos Zamboglou, Klinikum Offenbach, Strahlentherapie, Offenbach – Prof. Dr. med. Thomas G. Wendt, Klinik für Radiologie, Abteilung für Strahlentherapie, Jena / Prof. Dr. med. R. Bonnet, Zentralklinikum Bad Berka, Klinik für Pneumologie, Bad Berka – Dr. med. Silke Schüttrumpf, Georg August Universität Göttingen, Hämatologie und Onkologie, Göttingen / Dr. W. Körber, Evangelisches Krankenhaus Göttingen-Weende, Standort Lenglern, Abteilung Pneumologie, Bovenden – Dr. med. Christoph Jung, Gemeinschaftspraxis, Traunstein – Prof. Dr. T. Wiegel, Strahlentherapie Universitätsklinikum Ulm, / Dr. C. Schumann, Innere Medizin II, Universitätsklinikum Ulm, Ulm – Dr. med. Monika Serke, Helios Klinikum, Berlin ***(until mid of 2008)*** Lungenklinik Hemer, Hemer ***(since end of 2008)*** – Prof. Dr. med. Jörg Mezger, St.-Vincentius Klinik - Hämatologie, Onkologie, Immunologie - Medizinische Klinik Abteilung 2, Karlsruhe
Study centre(s):	45 German participating centres (which 34 recruiting): – Medizinisches Klinikum, Pneumologie, Klinikum der LMU, Ziemsenstr. 1 in 80336 München – Universitätsklinikum Rostock, Klinik und Poliklinik für Strahlentherapie, Südring 75 in 18059 Rostock – Strahlentherapie der Universität Würzburg, Josef-Schneider-Str. 2-11 in 97070 Würzburg – Krankenhaus Donaustauf, Pneumologie, Ludwigstr.68 in 93093 Donaustauf – Universität Regensburg, Strahlentherapie, Franz-Josef-Strauß-Allee 11 in 93042 Regensburg – Vivantes Klinikum Neukölln, Klinik für Strahlentherapie, Rudower Str. 48 in 12351 Berlin – Paracelsus Klinik Ruit, Hedelfinger Straße 166 in 73760 Ostfildern – Krankenhaus Nordwest, Steinbacher Hohl 2-26 in 60488 Frankfurt – Pius Hospital, Strahlentherapie & internistische Onkologie, Georgstr. 12 in 26121 Oldenburg – Klinikum Offenburg, Med. Klinik II, Ebertplatz 12 in 77654 Offenburg

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	– Universitätsklinikum Marburg, Strahlentherapie, Baldingerstraße in 25053 Marburg – Helios Klinikum Wuppertal, Strahlentherapie, Heusnerstraße 40 in 42283 Wuppertal – Klinik und Poliklinik für Radiotherapie und Radioonkologie, Stephan Str. 9a in 04103 Leipzig. – Leopoldina Krankenhaus / Strahlentherapie, Gustav-Adolf-Str. 8 in 97422 Schweinfurt – Klinikum am Eichert, Radioonkologie, Eichertstr. 3 in 73035 Göppingen – Klinikum Bayreuth, Preuschwitzer Str. 101 in 95445 Bayreuth / Bezirksklinikum Obermain Kutzenberg in 96250 Ebensfeld – Klinikum Ansbach, Radiotherapie, Escherichstr. 1 in 91522 Ansbach – Helios Klinikum, Emil von Behring GmbH, Walterhöferstr. 11 in 14165 Berlin – Städtisches Klinikum Braunschweig, Radioonkologie & Strahlentherapie, Celler Str. 28 in 38114 Braunschweig – Charité Campus Benjamin Franklin, Klinik und Hochschulambulanz für Radioonkologie und Strahlentherapie, Hindenburgdamm 30 in 12203 Berlin – Klinikum Darmstadt, Radioonkologie/Strahlentherapie, Grafenstr. 9 in 64283 Darmstadt – Klinikum Mannheim gGmbH, Strahlentherapie, Theodor-Kutzer-Ufer 1-8 in 68167 Mannheim – Universitätsklinik Köln, Strahlentherapie, Kerpener Str. 62 in 50924 Köln – Klinikum St. Marien; Mariahilfbergweg 7 in 92224 Amberg – Lungenfachklinik Immenhausen, Robert-Koch-Str. 3 in 34376 Immenhausen/Kassel – Medizinische Klinik V – Internistische Onkologie und Allergologie, Langhansstraße 2 in 35392 Gießen – Medizinische Hochschule Hannover, Zentrum für Innere Medizin, Abt. Pneumologie, Carl-Neuberg-Str. 1 in 30625 Hannover – Universitätsklinik des Saarlandes, Strahlentherapie, Kirchberg-Str. in 66424 Homburg – Klinikum St. Georg gGmbH, Robert-Koch-Klinik, Nikolai-Rumjanzew-Str. 100 in 04207 Leipzig – SRH Zentralklinikum Suhl, Strahlentherapie in 98527 Suhl – Klinikum Bremen-Mitte, Strahelntherapie, St. Jürgen-Str. 1 in 28205 Bremen – Kliniken der Stadt Köln gGmbH, Krankenhaus Merheim, Lungenklinik, Ostmerheimerstr. 200 in 51109 Köln – Klinik für Strahlentherapie und Radioonkologie, Heinrich-Braun-Krankenhaus Zwickau, Karl-Keil-Str. 35 in 08009 Zwickau – Pneumologische Klinik, Waldhog Elgershausen in 35753 Greifenstein – Krankenhaus der Barmherzigen Brüder, Prüfeninger Str. 86 in 93049 Regensburg – Klinikum Offenbach, Strahlentherapie, Starkenburgring 66 in 63069 Offenbach

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Name of active substance *(or ingredient)***:** Vinorelbine		

	– Klinik für Radiologie, Abteilung für Strahlentherapie, Friedrich-Schiller Universität, Bachstr. 18 in 07740 Jena / Zentralklinikum Bad Berka, Klinik für Pneumologie, Robert-Koch-Allee 9 in 99437 Bad Berka – Strahlenklinik, Universitätsstr. 27 in 91054 Erlangen – Strahlentherapie des Mutterhauses der Borromäerinnen, Feldtstraße 16 in 54290 Trier – Georg August Universität Göttingen, Hämatologie und Onkologie, Robert-Koch-Str. 40 in 37075 Göttingen / Evangelisches Krankenhaus Göttingen-Weende, Standort Lenglern, Abteilung Pneumologie, Pappelweg 5 in 37120 Bovenden – Gemeinschaftspraxis Dr. Jung, Wasserburgstr. 29 in 83278 Traunstein – Innere Medizin - Hämatologie / Onkologie - Palliativmedizin, Med. Klinik 3, Klinikum Leverkusen gGmbH, Am Gesundheitspark 1 in 51375 Leverkusen – Strahlentherapie Universitätsklinikum Ulm, Albert-Einstein-Allee 23 in 89081 Ulm / Innere Medizin II, Universitätsklinikum Ulm, Albert-Einstein Allee 23 in 89081 Ulm – Lungenklinik Hemer, Theo-Funccius-Str. 1 in 58675 Hemer – St.-Vincentius Klinik - Hämatologie, Onkologie, Immunologie - Medizinische Klinik Abteilung 2; Südendstraße 32 in 76137 Karlsruhe
Publication (reference):	ESMO 2010, ASCO, 2012, DGHO 2012.
Studied period:	First enrollment: 29/07/2005 Last enrollment: 13/05/2009 Last completed: 04/10/2009 **Planned**: Approximately 376 patients to be recruited to get 282 evaluable randomised patients in 36 months. **Analyzed**: In agreement with the study investigators, it was decided to stop the accrual after 46 months. The enrolment period was longer than planned because of the rarity of the type of the patient population to be included in a protocol of chemo-radiotherapy. The final analysis was performed including a total of 288 recruited patients, of whom 279 were treated with concomitant chemo-radiotherapy and 201 were randomized.
Phase of development:	Randomized phase III
Objectives:	**Primary objectives:** ❖ To compare progression-free survival in both arms. **Secondary objectives:** ❖ To evaluate the response rate, overall survival in both arms ❖ To evaluate the safety profile in both arms ❖ To assess QoL by LCSS
Methodology:	Open-label, randomized, multicentric phase III trial. Randomization will be stratified according to center and stage of the disease (IIIA or IIIB).
Number of patients (planned and analyzed):	Planned: Approximately 376 patients to be recruited to get 282 evaluable randomized patients. Analyzed: 288 enrolled in the four year planned study inclusion period.
Diagnosis and main criteria for inclusion:	Diagnosis: Non-Small Cell Lung Cancer (NSCLC) ❖ Patients aged between 18 and 75 years; ❖ Histologically or cytologically (fine needle aspiration) proven non-small cell lung cancer (NSCLC); ❖ Untreated locally advanced inoperable stage IIIA (only N2) or untreated locally advanced inoperable stage IIIB amenable to radical radiotherapy to a dose of 66 Gy;

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	❖ Patients with a Karnofsky Performance Status ≥ 80%; ❖ Adequate pulmonary function; ❖ Life expectancy > 12 weeks; ❖ Patients without weight loss > 10% within the previous 3 months ❖ Adequate bone marrow, hepatic and renal functions ❖ Presence of at least one measurable lesion (RECIST criteria) ❖ Absence of psychological, familial, sociological or geographical conditions potentially hampering compliance with the study protocol ❖ Written informed consent before completing any study-related procedure ❖ Women of childbearing potential must be using a medically accepted method of contraception ❖ Fertile men had to use an effective method of birth control if their partners are women of childbearing potential.
Exclusion criteria	❖ Patients with NSCLC stage IV; ❖ Patients with NSCLC stages I, II, IIIA (except N2); ❖ Patients with NSCLC stage IIIB: o with malignant pleural effusion; o with tumor extent or location precluding radical radiotherapy as specified in the protocol; ❖ Symptomatic neuropathy (sensory) > grade 1 according to the NCI Common Toxicity Criteria; ❖ Hearing impairment ≥ Grade 2; ❖ Concomitant/uncontrolled medical disorder (cardiac failure or myocardial infarction within the previous 3 months; uncontrolled hypertension or arrhythmia; uncontrolled hypercalcaemia; active infection requiring I.V. antibiotics within 2 weeks before the beginning of treatment); ❖ Weight loss > 10% within the previous 3 months; ❖ Pre-existing malignant pleural effusion ; ❖ Ascites or pericardial effusion ; ❖ Active secondary malignancy except appropriately treated carcinoma in situ of the cervix or skin basal cell cancer. Patients with a history of cancer and at least five years of uneventful follow up and no signs of recurrence may be eligible; ❖ Previous or concomitant treatment with other anticancer drugs during the last 5 years; ❖ Known hypersensitivity to the study drugs or to drugs with similar chemical structures; ❖ Concomitant treatment with systemic corticosteroids except chronic treatment lasting more than 1 month at low doses (≤20 mg/day of methyl prednisolone or equivalent); ❖ Significant malabsorption syndrome or disease affecting the gastrointestinal tract function and the absorption of oral drugs; ❖ Women if pregnant or breast-feeding or with positive pregnancy test at inclusion; ❖ Male or female of childbearing potential unwilling or unable to use a medically accepted method to avoid pregnancy during the 2 months preceding the start of study treatment, throughout the study period and at least 3 months following the last dose of study treatment; ❖ Participation to another clinical trial with any investigational drug study (whatever the use, curative, prophylactic or diagnostic intent) within 30 days prior to registration;
Test product, Dose, and Mode of administration: **Concomitant chemo-radiotherapy**	• **Chemotherapy** (2 cycles q 28 days) defined as cycle 1 & 2: **Oral Vinorelbine** **Cisplatin** 50 mg/m2 d1, d8, d15 20 mg/m2/d from d1 to d4 • **Radiotherapy**: 66 Gy (total dose), administered in fractions of 2 Gy/day for 6.5 consecutive weeks (5 fractions/week) starting on day 1 of the first chemotherapy cycle.
Test product, Dose, and Mode of administration: **Consolidation therapy**	• **Chemotherapy** (2 cycles q 21 days) defined as cycle 3 & 4: **Oral Vinorelbine** 60 mg/m2 d1, d8 for cycle 1 and 80 mg/m2 d1 and d8 for cycle 2

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	Cisplatin 80 mg/m2 day 1 plus Best Supportive Care **OR** **Best Supportive Care** Antiemetics and supportive therapy were given according to the institution's routine. Systematic antiemetic treatment with 5-HT3 antagonist had to be administered before oral vinorelbine. It was recommended to take oral vinorelbine with some food.
Batch Numbers:	**NAVELBINE ORAL 20 mg:** PC20050116/ 04-07 batch AQ20118 PC20050116/ 04-09 batch AQ20139 PC20050116/ 05-07 batch AQ30119 PC20050116/ 10-07 batch AQ20118 PC20050116/ 10-07 batch AQ20122 PC20050116/ 10-07 batch AQ20139 PC20050116/ 11-09 batch AQ20146 PC20050116/ 12-06 batch AQ20116 **NAVELBINE ORAL 30 mg:** PC20050116/ 04-09 batch AQ30138 PC20050116/ 03-07 batch AQ30117 PC20050116/ 04-09 batch AQ20138 PC20050116/ 04-09 batch AQ30138 PC20050116/ 04-09 batch AQ30147 PC20050116/ 05-07 batch AQ30119 PC20050116/ 05-07 batch AQ30138 PC20050116/ 05-09 batch AQ30138 PC20050116/ 09-08 batch AQ30119 PC20050116/ 09-08 batch AQ30125 PC20050116/ 09-09 batch AQ30125 PC20050116/ 09-10 batch AQ30160 PC20050116/ 09-10 batch AQ30160 PC20050116/ 11-08 batch AQ30147 PC20050116/ 11-08 batch AQ30147 PC20050116/ 11-09 batch AQ20146 PC20050116/ 11-09 batch AQ30147 PC20050116/ 11-09 batch AQ30148 PC20050116/ 12-06 batch AQ20116
Duration of treatment:	All patients were treated with oral vinorelbine together with cisplatin concurrently with RT for 2 cycles, unless occurrence of documented progressive disease or unacceptable toxicity. RT was planned to be administered during a period of 6.5 weeks, starting on day 1 of the 1st chemotherapy day. After the CT-RT regimen, randomization was performed in responding or stable disease patients between consolidation therapy: either chemotherapy plus Best Supportive Care for 2 cycles (Arm A) or Best Supportive Care alone (Arm B).
Criteria for evaluation: **Efficacy:**	- Assessments of measurable and not measurable lesions carried out at baseline and every two treatment cycles (after CT-RT treatment and after consolidation CT) by using RECIST criteria. - Assessment performed 4 weeks after documentation of a partial or complete response to confirm it. - Regular follow up at 2 month intervals during the first year after completion of treatment and then every 3 months until progression of the last evaluable patient.
Safety:	- Physical examination including vital signs, body weight and performance status - Complete blood cell count - Serum chemistry - Regular reporting of adverse event, graded by using the NCI Common Toxicity Criteria (version 2.0).
Statistical methods:	- All registered patients included in the intent-to-treat-analysis.

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- Patient receiving at least one administration of study treatment analyzed for safety unless the patient is lost to follow-up immediately after the start of treatment.
- Estimation of the number of patients based on the following clinical hypotheses :
  - Median progression-free survival for the Arm A: 9 months,
  - Median progression-free survival for the Arm B: 6 months,
  - accrual time is assumed: 36 months,
  - follow-up time after the last recruitment is 12 months.

Evaluable patients: The evaluable population is a subset of the ITT population. To be included in the evaluable population, the patients had to be eligible, evaluable and treated in the arm assigned by randomization. To be eligible a patient should have had no major protocol deviations from inclusion and exclusion criteria. To be evaluable all baseline lesions of a patient must have been assessed at least once after the second cycle, with the same method of measurement as baseline.

Main patient's characteristics

	CT-RT N=279	**Consolidation = 201**	
		CT+BSC N=96	**BSC N=105**
Male / female (%)	71.0 / 29.0	71.9 / 28.1	71.4 / 28.6
Med age yrs (range) ≥ 60 years, N (%) < 60 years, N (%)	60.3 (33.9-75.7) 143 (51.3) 136 (48.7)	60.3 (34.1-75.9) 52 (54.2) 44 (45.8)	59.5 (40.4-75.1) 51 (48.6) 54 (51.4)
Med PS* % (range) ≤ 80%, N (%) > 80%, N (%) Missing N (%)	90 (80-100) 44 (15.8) 234 (83.9) 1 (0.4)	90 (50-100) 24 (25.0) 60 (62.5) 12 (12.5)	90 (70-100) 26 (24.8) 73 (69.5) 6 (5.7)
Co-morbidities°, % 0 / 1 / 2 / ≥ 3	17.6/37.3/36.9/8.2	20.8/41.7/30.2/7.3	19.0/33.3/40.0/7.6
Histology, % squam/Adk/ L. cell/ NOS	53.0/36.2/6.8/5.0	54.2/36.5/7.3/2.1	52.4/37.1/7.6/3.9
Stage, % IIIA / IIIB	17.6 / 82.4	20.8 / 79.2	19.0 / 81.0

*: Karnofsky; °: 1 point each for respiratory, cardiovascular, renal and metabolic comorbidity.

Efficacy results

	CT-RT=279 (Eval 249)	**Consolidation = 201**		**P**
		CT+BSC N=86	**BSC N=102**	
ORR ITT, % (95% CI) ORR Eval, % (95% CI)	55.6 (49.5-61.5) 60.7 (54.3-66.9)	29.2 (20.4-39.4) 36.8 (26.0-48.6)	24.8 (16.8-34.2) 29.2 (20.0-39.8)	0.48 0.30
DCR ITT, % (95% CI) DCR Eval, % (95% CI)	78.5 (73.2-83.2) 86.0 (80.9-90.1)	66.7 84.2	56.2 66.3	0.12 0.0084

	Consolidation		**p**
	CT+BSC N=86	**BSC N=102**	
Median PFS* ITT, months (95% CI)	6.4 (5.0-8.7)	5.5 (3.8-7.4)	0.63**
Median OS* ITT, months (95% CI)	20.8 (13.5-25.3)	18.5 (13.6-24.7)	0.87****
2 year Survival, %	41.6	41.1	
4 year Survival, %	25.2	21.4	

*calculated from time of randomization (Median time registration to randomization 3.0 / 2.9 months) **stratified log-rank test

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Safety results

Grade 3/4 haematological toxicity (NCI-CTC) per patient

	CT-RT Phase N=279		ARM A: CT+BSC N=86		ARM B: BSC N=87	
	Gr 3	Gr 4	Gr 3	Gr 4	Gr 3	Gr 4
Anemia	2.5	0.7	3.5	-	1.1	-
Leucopenia	10.8	7.5	20.9	5.8	-	-
Neutropenia	6.5	4.7	11.6	10.5	-	-
Thrombocytopenia	2.5	-	1.2	-	-	-
Febrile neutropenia (Pizzo)	1.4		1.0		-	

Grade 3/4 non hematological toxicity (NCI-CTC) per patient

	CT-RT Phase N=279		ARM A: CT+BSC N=86		ARM B: BSC N=87	
	Gr 3	Gr 4	Gr 3	Gr 4	Gr 3	Gr 4
Nausea / Vomiting	**5.0 / 3.2**	- / -	**2.3 / 3.5**	- / -	- / -	- / -
Fatigue	**2.9**	**0.4**	**1.2**	-	-	-
Anorexia	**2.9**	**0.7**	-	-	-	-
Pneumonia	**2.2**	**0.4**	-	-	1.0	-
Pneumonitis	-	-	-	-	2.0	-

Dose intensity and relative dose intensity

	CT-RT Phase=279	**Consolidation Phase N=188**	
		CT+BSC N=86	**BSC N=102**
First cycle Second cycle	279 (100%) 255 (91.4%)	86 (100%) 78 (90.7%)	102 (100%) 97 (95.1%)
Median number of cycles	2	2	2
Median relative dose intensity of NVBo, % (range)	94.1% (14.7-118.4)	93.3% (48.2-117.7)	-
Median relative dose intensity of CDDP, % (range)	98.5% (37.9-115.5)	96.5% (37.3-106.1)	-

Responders according to prognostic factors

	CT-RT Phase=155	**Consolidation Phase N=54**	
		CT+BSC N=28	**BSC N=26**
Age < 60 y / ≥ 60 y	54.4 / 56.6	27.2 / 30.8	22.2 / 27.5
Gender male / female	56.1 / 54.3	24.6 / 40.7	22.7 / 30.0
PS 80 / 90 / 100	45.5 / 56.5 / 58.2	33.3 / 20.6 / 34.6	26.1 / 17.0 / 30.8
Histology squamous / adeno	60.5 / 54.5	34.6 / 25.7	23.6 / 28.9
Stage IIIA / IIIB	51.0 / 56.5	20.0 / 31.6	30.0 / 23.5
> 5% baseline weight loss: y/n	56.3 / 47.8	16.7 / 36.7	29.3 / 21.9

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Response to consolidation therapy according to previous response

N=288	**CT-RT period N=279**	**Consolidation N=201**	
		CT+BSC N=96	**BSC N=105**
Median PFS ITT (m (95% CI))	N Pts with OR (N=142)	6.6 (5.0-8.7)	5.8 (3.9-8.2)
	N Pts with SD (N=56)	6.4.(4.6-13.0)	4.4 (2.0-9.5)

General Conclusion

- Concurrent NVBo-CDDP + RT followed by consolidation is an effective treatment for unresectable stage III NSCLC:
  - CT-RT period: ORR 55.6% (ITT), DCR 78.5% (ITT)
- The toxicity profile compares favorably to other regimens
- Oral vinorelbine may decrease planning constraints during CT-RT
- Consolidation with NVBo+CDDP:
  - Significantly improves DCR in evaluable patients (p=0.0084)
  - Prolongs PFS for patients with SD after CT-RT
  - No significant survival benefit has been reported in unselected patients
- The overall survival results in the ITT population are in line with previously published results

Date of report: 28. May 2013